10.5152/turkjnephrol.2021.4547

Original Article

Turkish Journal of Nephrology

# Outcomes of Renal Transplantation in End-Stage Renal Disease Patients with Nonischemic Very Low Ejection Fraction Heart Failure

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## Abstract

**Objective:** Transplantation in end-stage renal disease (ESRD) patients with very low left ventricular ejection fraction (LVEF) heart failure (HF) is a challenging issue, owing to the potential risk of morbidity and mortality, perioperatively. Although patients' survival and worse graft outcomes can be predicted, there is no evidence to claim worse outcomes, especially in patients with nonischemic heart failure.

**Materials and Methods:** A total of 110 ESRD patients were enrolled in the study, and they were divided into 3 groups. Group 1 (n=10) included ESRD patients with very low LVEF (<45%) HF who could not undergo allograft transplantation (on the waitlist or with immunological barriers to receive a living-related graft), Group 2 (n=20) included ESRD patients with very low LVEF HF who underwent allograft transplantation, and Group 3 (n=80) included ESRD patients who received an allograft and had no history of HF. Patients with EF between 45-55% were excluded.

**Results:** The mean follow-up period was 15.1±3.1 months. Two patients from Group 1 died (Group 1 vs Group 2 and 3; p<0.05). Delayed graft function rates, one-year graft functions, graft loss, and one-year mortality rates were similar in Group 2 and 3.

**Conclusion:** ESRD patients with a nonischemic low LVEF HF can receive all advantages of an allograft transplantation as recipients with normal LVEF.

**Keywords:** Heart failure, kidney transplantation, mortality

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**Received:** 27.07.2020 **Accepted:** 22.10.2020

**Cite this article as:** Demir ME, Merhametsiz Ö. Outcomes of Renal Transplantation in End-Stage Renal Disease Patients with Nonischemic Very Low Ejection Fraction Heart Failure. Turk J Nephrol 2021; 30(1): 70-6.

## INTRODUCTION

With its gradually increasing prevalence, end-stage renal disease (ESRD) is becoming an increasingly important public health issue day by day. The annual growth rate of ERSD is currently at 8%, which is far more than the population growth rate of 1.3% (1). In order to prevent or at least minimalize the rate of morbidity and mortality of the disease, clinicians are striving to deliver the best choice of renal replacement modality to eligible patients. It is well known that renal transplantation (RTx) from a deceased or living-related donor is still the best choice of treatment of the disease for the majority of the patients (2, 3). The fact remains that the organ donation pool's shortage is the most common obstacle in the provision of the best health care to those patients.

Cardiovascular diseases (CVDs) are the leading cause of mortality in developed countries and are considered a financial burden on the health systems around the world (4, 5). CVDs are the leading cause of morbidity and mortality in patients with ESRD. ESRD and CVDs inevitably coexist in most patients due to common risk clusters, and sometimes it is difficult to describe which one occurred first.

CVD-related morbidity and mortality rates have a positive correlation with CKD stages, and the patients on dialysis modalities are at the highest risk of mortality (6). Renal transplantation provides many clinical benefits to patients with ESRD and CKD. CVD accounts for approximately 35-50% of all-cause related mortality in kidney

transplantation. CVD-related mortality risk is at least twice as high in an age-adjusted sample compared to the general population, however, it is considerably lower than the age-adjusted dialysis population (7, 8).

CKD, particularly CKD stage 5 (ESRD), is a major risk factor for the development of CVDs, and the adverse impact of the uremic state contributes to the worsening of cardiac functions (9). Ischemic heart disease may obtain fewer benefits from restoration of uremic states compared with nonischemic uremic cardiomyopathy-related heart failure (8). In contrast, both those groups may take advantage of a well-functioning kidney graft after transplantation (10). In addition, Kidney Disease Improving Global Outcomes (KDIGO) Guidelines for transplant candidates suggest that patients with uncorrectable, symptomatic heart disease (severe coronary artery disease, LVEF <%30, and severe valvular disease) be excluded from kidney transplantation unless there are mitigating factors that give the patient an estimated survival which is acceptable according to national standards (11).

Low ejection fraction hearth failure (HF) (the term is also used for left ventricular systolic dysfunction [LVEF]) is a compelling issue of kidney transplantation. Many centers avoid operating such patients since they are at higher morbidity and mortality risk in the perioperative period and also as they are at potential risk of immunosuppression regimens. Nevertheless, we believe patients with low ejection fraction heart failure might have a chance of receiving a kidney allograft and benefit from the advantage of a "uremic state"- free life.

Here, we present our single-center experience on patients with very low ejection fraction HF who received a kidney allograft from a deceased or living donor.

## MATERIALS AND METHODS

This single-center retrospective observational cohort study was conducted between 2016 and 2018 at the department of nephrology and organ transplantation. A total of 110 patients were enrolled in the study. Individuals were divided into 3 groups: Group 1 (n=10) included ESRD patients with low ejection fraction HF (EF <45%) who did not undergo renal transplantation. In this group, recipient candidates were selected from the patients who were admitted for a deceased-related allograft transplantation or patients who had a living donor but faced with immunologic problems, Group 2 (n=20) included ESRD patients with low ejection fraction HF (EF <45%) who underwent renal transplantation, and Group 3 (N=80) had ESRD patients with normal ejection fraction and no HF history who underwent renal transplantation.

### Main Points

- ESRD patients with nonischemic very low left ventricular ejection fraction (LVEF) heart failure may receive benefits of renal transplantation as much as ESRD patients with normal LVEF.
- Perioperative mortality, delayed graft function, and one-year graft survival and functions do not differ between recipients with nonischemic low LVEF and normal LVEF.
- Clinicians should be aware of risk disparities between ischemic and nonischemic LVEF heart failure before transplantation.

### Study Design and Patient Selection

In our design, we considered patients with LVEF <45% as very low EF HF (Figure 1). "ESC guidelines of 2016 for the diagnosis and treatment of acute and chronic heart failure" classify HF on echocardiographic findings as reduced LVEF (<40%), mid-range LVEF (40-49%), and preserved LVEF (≥50%) (12). Despite this fact, we aimed to expand the number of cases and included 3 cases with LVEF between 40 and 45%. We also determined a free range of EF (LVEF 45-55%) to obtain a clear benefit between individuals with LVEF <45% and LVEF >55%.



We aimed to reveal at least 1-year outcome of the kidney allograft performed in recipients with very low ejection fraction HF. Recipients with stable ischemic or nonischemic heart failure with LVEF 45-55% (15 recipients and most of them were diabetics) were excluded. Recipients with frequent acute rejection episodes and urinary infections, polyoma BK-Virus associated nephropathy, and cytomegalovirus disease, which are independent risk factors for allograft functions, were also excluded. Recipients with very low LVEF were relatively young (mean; 32.68±11.40), and thus, we excluded older recipients (>65 years) and recipients who had older donors (>65 years) in normal LVEF group. As mentioned above, we excluded individuals with LVEF in the range of 45-55%, to reveal if there is a clear benefit in those with very low EF HF compared with patients with normal EF. Finally, we identified 100 kidney recipients who met all eligibility criteria.

Patients with low ejection fraction were investigated for an ischemic component of heart failure. All patients with LVEF underwent percutaneous coronary intervention, and if they had critical coronary artery disease, they were excluded. Patients who had longstanding diabetes and many noncritical coronary occlusions with a history of a recent coronary artery stenting (independent of stenting count) were postponed for 6 months and were subsequently reevaluated for transplantation. Patients who had no history of diabetes or had a short-period of diabetes with a recent coronary artery stenting anamnesis were postponed for 3 months and afterwards reevaluated for transplantation. In patients with LVEF but no evidence of ischemia in coronary angiography, a cardiac septal biopsy was performed simultaneously. In addition, these patients were assessed for cardiac fibrosis by MRI. MRI was performed using gadolinium as a contrast agent, and all patients were informed about nephrogenic systemic fibrosis, which is a rare adverse reaction of the agent. No adverse reaction was noted in posttransplant follow-ups.

**Table 1.** Summary of epidemiological and clinical features of patients with ESRD

| Labels and parameters | 110 patients with ESRD |
|---|---|
| Age, years | 35 (13-71) |
| Male/female | 75/35 |
| Hemodialysis duration, months | 13 (0-170) |
| Preoperatively eGFR, mL/min | 8.10±2.90 |
| Renal transplantation | |
| Preemptive | 22 (20%) |
| Non-preemptive | 78 (71%) |
| Non-RTx | 10 (9%) |
| Immunological assessment | |
| High risk | 11 (11%) |
| Low risk | 89 (89%) |
| Induction treatment | 98 with ATG |
| | 2 with basiliximab |
| Maintenance therapy | 88 recipients; tacrolimus + mycophenolate mofetil + prednisone |
| | 12 recipients; low dose tacrolimus + mTORi + prednisolone (the switching protocols were individualized) |
| Follow-up (mo) | 15±3.16 |
| Preoperatively EF in the Groups (%) | |
| Group 1 | 35.90±6.47 |
| Group 2 | 34.90±8.50 |
| Group 3 | 63.52±2.44 |
| Hypertension, n (%) | 66 (60) |
| Diabetes mellitus, n (%) | 18 (16.4) |
| Glomerular diseases, n (%) | 12 (11) |
| Others, n | 2 cases; Alport syndrome<br>1 case; lupus nephritis |
| | 1 case; cystinosis |
| | 1 case; primary hyperoxalosis |
| | 1 case; aHUS |
| | 1 case, urolithiasis |
| | Remain; unknown |
| 1-year mortality, n | Two in Group 1 |
| | Compared to the group 2 and 3; p<0.05 |
| Graft origin, n | |
| Deceased | 12 (12%) |
| Living | 88 (88%) |

eGFR: estimated glomerular filtration rate; RTx: renal transplantation; EF: ejection fraction; aHUS: atypical hemolytic uremic syndrome; ATG: anti-thymocyte globulin



Uremic cardiomyopathy may be a consequence of inadequate dialysis treatment. Therefore, all recipient candidates were evaluated for inadequate dialysis treatment. After an intensive hemodialysis therapy (providing euvolemic state, restoring anemia, etc.), all recipients were reevaluated using echocardiography for checking LVEF. Preoperatively, the last two echocardiography that were performed in the last two weeks were evaluated. Echocardiographic evaluation was conducted by a single experienced cardiologist who was a member of our organ transplantation team.

Postoperatively, recipients were evaluated for delayed graft function, early and 1-year mortality (death in 3 and 12 months after transplant), primary non-function grafts, graft functions in months 1, 3, 6, and 12 after transplant.

All patients were scheduled for a standard immunosuppression regimen that consisted of anti-thymocyte globulin (ATG) induction and prednisolone + calcineurin inhibitor (CNI) + mycophenolate mofetil-based maintenance treatment. In addition, all recipients received 7 mg/kg/day of methylprednisolone for three days.

**Table 2.** Comparison of graft functions in Group 2 and Group 3

| | Group 2 (RTx- Low EF HF) n=20 | Group 3 (RTX- non HF) n=77 | p |
|---|---|---|---|
| Age, years | 32.68±11.40 | 38.13±15.90 | 0.19 |
| Hemodialysis duration, month | 11 (0-120) | 18 (0-170) | 0.39 |
| eGFR, mL/min (before RTx) | 7.96±2.78 | 8.10±3.19 | 0.87 |
| eGFR, mL/min (month 1) | 80.52±30.78 | 81.25±32.88 | 0.94 |
| eGFR, mL/min (month 3) | 83.03±31.47 | 85.44±22.38 | 0.77 |
| eGFR, mL/min (month 6) | 78.50±31.68 | 76.02±20.72 | 0.76 |
| eGFR, mL/min (month 12) | 79.44±35.53 | 79.43±19.08 | 0.99 |
| Antihypertensive use, n | 15 | 30 | 0.10 |
| Diabetes Mellitus, n | 4 | 11 | 0.11 |
| Graft loss, n | 0 | 3 | 0.15 |
| Immunological assessment | Only 2 recipients with high immunological risk | 9 recipients with high immunological risk. 2/3 of graft loss occurred in recipients with high immunological risk | Group 2 vs Group 3 for immunological risk; p=0.89 |
| Mortality, n | 0 (15.1±3.16 month) | 0 (14.6±2.46 month) | |



Patients were also assessed for cardiac function at every visit, but cardiac performance and recoveries will be considered in future study. Hence, the outcomes of echocardiographic findings were not included in this study.

The ethical committee approval was obtained for the conduction of the study from the Clinical Research Ethics Committee of Yeni Yüzyıl University (Approval Date: May 14, 2020; Approval Number: 918). The study is designed retrospectively, thus an informed consent form is not available.

The recipients who still needed dialysis within postoperative 1 week were labeled as delayed graft function (DGF).

Recipients with donor-specific antibody positivity (MFI >5000 for any matching HLA antigens, by Single Bead Antigen assay) were labeled as "at high immunological risk".

Survival time was considered from the day of measurement of last LVEF, during the waitlist, to the next 12-15 months, for Group 1 (if transplanted, were switched to Group 2).

**Statistical Analysis**

The Statistical Package for the Social Sciences version 18.0 (SPSS Inc.; Chicago, IL, USA) was utilized to compare all data. All descriptive parameters were listed using mean values with±-standard deviation for parametric and median values (minimum and maximum) for nonparametric. Parametric data were compared using the "independent samples t-test", and nonparametric data were compared using "Kruskal-Wallis test". Chi-square test was used to compare categorical variables. P<0.05 assigned as statistically significant in the range of 95% confidence interval.

## RESULTS

A total of 110 patients (75 males, 35 females) with ESRD were enrolled in the study. The mean age was 37.05±14.02. Two patients in Group 1 died during the follow-up period. In our ESRD population, only 18 patients had diabetes mellitus (16.36%). One of the patients who died had diabetes mellitus and had a relatively longer dialysis duration. Epidemiological and clinical features of all individuals are given in Table 1. Two patients had to receive monoclonal IL-2 receptor antagonist (basiliximab) instead of ATG induction, due to ATG-related severe reactions.

DGF occurred in only 6 patients and all had received their allograft from a deceased-related donor. DGF developed in 4 patients who preoperatively had low EF HF, and 2 DGF events occurred in normal EF recipients (p=0.48).

Graft functions in both low ejection fraction HF and normal EF (non-HF) groups were similar (Table 2) in the 1-year follow-up. In Group 3, three graft loss were realized, one due to primary nonfunctioning kidney, one due to severe persistent pyelonephritis (allograft nephrectomy was performed in the 6$^{th}$ month), and one due to allograft rejection (in 8$^{th}$ month).

## DISCUSSION

Ischemic and nonischemic heart failure may complicate the assessment of kidney recipient candidates perioperatively. In particular, there are claims that patients with low ejection fraction heart failure are not appropriate for renal transplantation

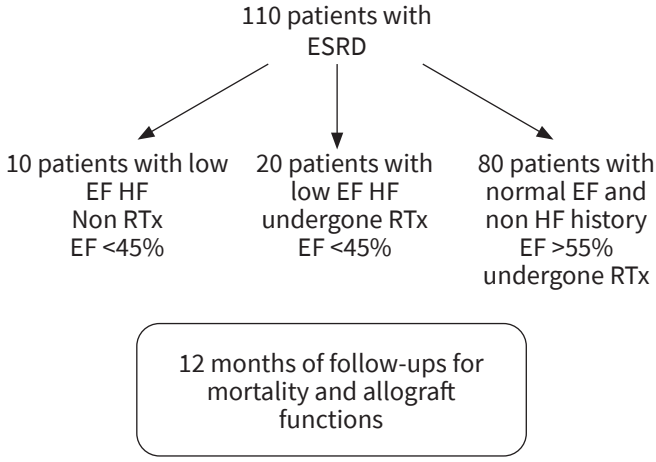


**Figure 1.** Design of the group selection

ESRD: end-stage renal disease; EF: ejection fraction; HF: heart failure; RTx: renal transplantation



because of relatively high rates of morbidity and mortality potential and a shorter life expectancy perioperatively. Here, we establish that patients with low LVEF HF who do not have an ischemic component of cardiomyopathy can also benefit from all advantages of allograft transplantation as much as recipients with normal LVEF, with no associated risk of a higher rate of mortality; at least within the first year of the post transplantation period.

In CKD and ESRD population that needs renal replacement treatment, diabetes is the primary cause of ESRD. In our population, hypertension was more common. This might be due to: (1) a delayed diagnosis of CKD and accompanying of HT to the advanced stages of the kidney disease, (2) the young population might have undiagnosed hypertension until the development of ESRD (our cohort was relatively younger), and (3) undiagnosed hereditary diseases.

The prevalence of CVDs is markedly increased in the CKD population, however, the USRDS data report suggests that ischemic events might not be the major factor leading to mortality in this population (13). Outcomes of a prospective multi-center cohort study on 432 dialysis patients (followed for a mean 41 months) revealed that the median survival of subjects with chronic heart failure (CHF) at baseline (at the onset of hemodialysis) was 36 months compared with 62 months in subjects without CHF. In addition, 76 of 299 patients (25%) who did not have a baseline CHF developed CHF during the course of their dialysis. Interestingly, when risk factors for the development of de novo congestive heart failure were analyzed by Cox's Proportional Hazards Model, hemoglobin fall, serum albumin fall, systolic, and diastolic blood pressure, age, and diabetes mellitus had a greater relative risk than old ischemic heart disease (14). This may indicate a unique milieu of hemodialysis which contributes to the development of de novo congestive heart failure. Even asymptomatic cardiac function in kidney transplant candidates who are on waiting list carries a substantial risk of mortality (15) Harnett et al. (14) argue that survival of dialysis patients may decrease by as much as 50% after diagnosis of CHF. In addition, with regard to hemodialysis treatment, appropriate volume removal, restoration of uremic milieu, secondary hyperparathyroidism, and correction of abnormal level of hemoglobin fall increase patients' survival (16). In this study, 2 renal transplant candidates with low ejection fraction HF (<45) died in the waiting list and that roughly may portend 20% of mortality for patients with low ejection fraction HF on the maintenance hemodialysis treatment.

In the past, left ventricular systolic dysfunction was considered as a contraindication to a kidney transplant. At present, it is still a usual approach to consider ESRD patients with systolic heart failure to be at high risk for surgery, and there is reluctance on the majority part of cardiologists and maybe some nephrologists to refer dialysis patients with low ejection fraction HF for kidney transplantation. However, the trend of accepting ESRD patients with low LVEF to transplant programs is increasingly emerging; favorable outcomes of perioperative periods of these patients and improvement of LV systolic function after allograft transplantation have encouraged us to perform more transplantations in ESRD patients with very low ejection fraction HF. In this study, 11 of 20 patients had LVEF ≤30%, and one of them had an LVEF ≤%20; the patient reached a normal LVEF after 12 months of renal transplantation. However, it should be considered that our cohort involved relatively younger individuals compared to the cases included in previous studies. Ravinder et al. reported outcomes of 103 recipients with ESRD and low ejection HF (LVEF<40%) who underwent renal transplantation. There was no perioperative death, and after transplantation, ~70% of patients achieved LVEF ≥50% (17). Their study population was quite different from ours; it included more patients who were older, more diabetics and hypertensive, and had previous coronary artery disease.

Renal transplantation can restore many complications related to ESRD. It is predicted that kidney transplantation will decrease the higher rates of cardiac dysfunction-related morbidity and mortality seen in dialysis patients. Evidence also indicates that renal allograft recipients with left ventricular dysfunction are at a higher risk of mortality and morbidity after renal transplantation than those with normal left ventricular systolic functions (18, 19). Rigatto et al. (20) reported that renal transplantation might correspond more to a state of "accelerated heart failure" than to "accelerated atherosclerosis in their study, but the prognosis was found similar between ischemic heart disease and de novo CHF. Additionally, Siedlecki et al. (21) claimed that systolic dysfunction is associated with increased risk for overall and cardiac-related death and nonfatal events after renal transplantation, an association independent of ischemic disease. Our results are substantially contrary to those suggestions. We believe that at least in renal transplant candidates with nonischemic heart failure outcomes could be predicted as excellent as those in

recipients with normal left ventricular systolic functions preoperatively. Also, in previous studies, the age of cohorts was relatively higher and this could result in us predicting higher all-cause mortality for all age groups. Briefly, in younger patients with nonischemic low ejection fraction heart failure, outcomes might be similar to the recipients with normal systolic functions.

DGF defines the need for dialysis in the first week of kidney transplantation and is associated with worse short-and-long-term graft outcomes. It is claimed to have the potential of promoting allograft rejection (21). Many donor- and recipient-related risk factors have been determined for DGF. The cardiac function of recipients has been suggested as a risk factor for DGF (22, 23). Even in very low EF HF patients, we did not face any DGF event. However, it should be taken into account that we specifically avoided the inclusion of ischemic-related LVEF patients to our study. Likely, because of the early recovery of the uremic myocardiopathy-related left ventricular systolic dysfunction, we did not encounter any DGF event.

## CONCLUSION

ESRD patients with nonischemic low ejection fraction HF may benefit from allograft transplantation as much as recipients with normal left ventricular systolic function. Clinicians should be aware of the quite different outcomes of uremic and ischemic cardiomyopathy when delivering the best renal replacement modality to the ESRD patients.

This single-center study bears some limitations, such as relatively low sample sizes and short follow-up duration. Besides, a different group consisting of recipients with ischemic heart disease-related heart failure could make outcomes more pertinent. In contrast, we think our study includes some important results for patients with very low ejection fraction HF.

**Ethics Committee Approval:** Ethics committee approval was received for this study from the Clinical Research Ethics Committee of Yeni Yüzyıl University (Approval Date: May 14, 2020; Approval Number: 918).

**Informed Consent:** Informed consent was not obtained due to the nature of this study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions**: Concept - M.E.D.; Design - M.E.D.; Supervision - M.E.D., Ö.M.; Data Collection and/or Processing - Ö.M.; Analysis and/or Interpretation - M.E.D., Ö.M.; Literature Search - Ö.M.; Writing - M.E.D., Ö.M.; Critical Reviews - M.E.D.

**Conflict of Interest:** The authors have no conflict of interest to declare.

**Financial Disclosure:** The authors declared that this study has received no financial support.

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