Section: Urology

Original Research Article

A RETROSPECTIVE STUDY OF RENAL TRANSPLANT OUTCOMES IN HCV-POSITIVE VERSUS HCV-NEGATIVE RECIPIENTS

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ABSTRACT

Background: HCV infection in kidney transplant recipients has historically been associated with poorer graft and patient outcomes, but direct-acting antiviral (DAA) therapy has made transplantation increasingly feasible in HCV-positive candidates. **Aims:** To compare renal graft function and clinical outcomes following kidney transplantation between HCV-positive recipients treated with direct-acting antiviral (DAA) therapy and HCV-negative recipients. **Study Design:** Retrospective observational comparative study. **Place and Duration of Study:** Department of Urology, Coimbatore Medical College Hospital, Tamil Nadu, India; study period as per institutional transplant records. **Materials and Methods:** Thirty-six kidney transplant recipients were studied, comprising 14 HCV-positive recipients who received DAA therapy and 22 HCV-negative recipients. Demographic and transplant-related characteristics, delayed graft function (DGF), acute rejection, serum creatinine at discharge, 6 months and 1 year, estimated glomerular filtration rate (eGFR) at 1 year, length of hospital stay, re-exploration, and patient/graft outcomes were compared between groups. **Results:** Mean age was comparable between HCV-positive and HCV-negative recipients (38.71 vs. 37.77 years; P=0.819). Serum creatinine fell from 2.67 to 1.57 mg/dL in HCV-positive recipients and from 2.51 to 1.55 mg/dL in HCV-negative recipients over discharge to 1 year, with no significant between-group differences at any time point (all P>0.05). Mean 1-year eGFR was similar between groups (59.71 vs. 60.05 mL/min/1.73 m²; P=0.898). DGF occurred less often in HCV-positive recipients (7.1% vs. 36.4%; P=0.062), and acute rejection rates were also comparable (7.1% vs. 13.6%; P=1.000). One death and one re-exploration occurred in each group. **Conclusion:** Kidney transplantation in appropriately selected HCV-positive recipients receiving DAA therapy was associated with graft function and patient outcomes comparable to HCV-negative recipients. These findings support DAA therapy as an effective strategy for optimizing transplantation outcomes in HCV-positive recipients. Larger prospective studies with longer follow-up are warranted.

INTRODUCTION

Hepatitis C virus (HCV) infection remains an important clinical concern in patients with end-stage kidney disease undergoing renal transplantation. HCV infection in kidney transplant recipients has historically been associated with increased risks of liver disease, cardiovascular complications, infections, acute rejection, graft dysfunction, and reduced patient and graft survival (Kidney Disease: Improving Global Outcomes [KDIGO] Hepatitis C Work Group, 2018, 2022). Consequently, HCV-positive patients were traditionally considered to have less favourable outcomes following transplantation.

The introduction of highly effective direct-acting antiviral (DAA) agents has substantially changed the management of HCV infection. DAAs can achieve sustained virological response in the vast majority of patients, with shorter treatment durations and considerably better tolerability than earlier interferon-based regimens (Chute et al., 2018; Sawinski et al., 2016; Sise et al., 2017). This has expanded the possibility of safely performing renal

transplantation in HCV-positive recipients and treating HCV infection either before or after transplantation.

Despite these advances, concerns remain regarding the impact of HCV infection and its treatment on early and intermediate-term renal allograft outcomes. Immunosuppressive therapy, potential drug–drug interactions between DAAs and calcineurin inhibitors, delayed graft function, acute rejection, and long-term graft function require careful evaluation (Lin et al., 2016). Furthermore, data from individual transplant centres, particularly from the Indian population, remain relatively limited (Goel et al., 2017; Taneja et al., 2018).

The present study was therefore undertaken to compare renal graft function and clinical outcomes in HCV-positive kidney transplant recipients receiving DAA therapy with those of HCV-negative recipients. The study specifically evaluated postoperative graft function, delayed graft function, acute rejection, complications, and patient and graft outcomes during follow-up. The objective was to determine whether, in the era of effective antiviral therapy, HCV-positive recipients can achieve outcomes comparable to those of HCV-negative kidney transplant recipients.

MATERIALS AND METHODS

2.1 Study Design and Setting

This was a retrospective observational comparative study conducted at the Department of Urology, Coimbatore Medical College Hospital, Tamil Nadu, India. The study included kidney transplant recipients who underwent renal transplantation during the study period and had adequate postoperative follow-up data.

2.2 Study Population

A total of 36 kidney transplant recipients were included in the study. Patients were divided into two groups according to their HCV status at transplantation:

- HCV-positive group: 14 recipients
- HCV-negative group: 22 recipients

Patients in the HCV-positive group received appropriate direct-acting antiviral (DAA) therapy as part of their management.

2.3 Data Collection

Clinical and transplant-related data were obtained from hospital records and the transplant database. The variables analyzed included age, sex, type of donor, underlying cause of end-stage kidney disease, duration of dialysis before transplantation, HCV status, DAA therapy, induction immunosuppression, and postoperative tacrolimus levels.

2.4 Assessment of Graft Function

Renal allograft function was assessed using serum creatinine at three predefined time points:

- At hospital discharge
- At 6 months after transplantation
- At 1 year after transplantation

The estimated glomerular filtration rate (eGFR) at 1 year was also recorded.

2.5 Post-Transplant Outcomes

The primary outcomes assessed were graft function and patient/graft survival. Secondary outcomes included:

- Delayed graft function (DGF)
- Acute rejection
- Biopsy-proven rejection where applicable
- Cytomegalovirus (CMV) infection
- BK virus infection
- Postoperative hematoma
- Ureteric leak
- Requirement for re-exploration
- Length of hospital stay
- Patient survival
- Graft survival

DGF was recorded based on the postoperative clinical course and requirement for dialysis during the early post-transplant period.

2.6 Statistical Analysis

The dataset contained 36 kidney transplant recipients, including 14 HCV-positive and 22 HCV-negative recipients. Continuous variables are presented as mean ± standard deviation and were compared using Welch's independent-samples t-test; the Mann–Whitney U test was also examined for robustness. Categorical variables are presented as number (percentage) and were compared using Fisher's exact test for sparse 2×2 tables or chi-square testing where appropriate. All tests were two-sided, with $P < .05$ considered statistically significant.

2.7 Ethical Considerations

The study was conducted in accordance with institutional ethical standards and the principles of the Declaration of Helsinki. Patient confidentiality was maintained throughout the study, and data were analyzed in anonymized form.

RESULTS

There were no statistically significant differences in baseline age, sex distribution, donor type, dialysis duration, or tacrolimus levels between HCV-positive and HCV-negative recipients (Table 1). Mean age was 38.71 ± 12.51 years in the HCV-positive group and 37.77 ± 10.84 years in the HCV-negative group ($P = .819$). Deceased-donor renal transplantation (DDRT) accounted for 8/14 (57.1%) HCV-positive and 15/22 (68.2%) HCV-negative recipients ($P = .723$).

Renal function outcomes were comparable between the two groups (Table 2). Mean serum creatinine at discharge was 2.67 ± 1.39 mg/dL in HCV-positive recipients versus 2.51 ± 1.30 mg/dL in HCV-negative recipients ($P = .729$). At 6 months, mean creatinine was 1.74 ± 0.52 versus 1.84 ± 0.52 mg/dL ($P = .585$), and at 1 year it was 1.57 ± 0.42 versus 1.55 ± 0.34 mg/dL ($P = .873$), respectively (Figure 1). Mean 1-year eGFR was also similar (59.71 ± 8.63 versus 60.05 ± 4.94 mL/min/1.73 m²; $P = .898$) (Figure 2).

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Delayed graft function occurred in 1/14 (7.1%) HCV-positive recipients compared with 8/22 (36.4%) HCV-negative recipients (P = .062), representing a non-significant trend toward less DGF in the HCV-positive group (Figure 4, Table 2). Acute rejection occurred in 1/14 (7.1%) versus 3/22 (13.6%) (P = 1.000; Figure 3), and biopsy was performed in 1/14 (7.1%) versus 2/22 (9.1%) (P = 1.000).

Postoperative complications were uncommon in both groups (Table 3). Re-exploration was required in 1/14 (7.1%) HCV-positive and 1/22 (4.5%) HCV-negative recipients (P = 1.000). Definite hematoma occurred in 0 versus 1 recipient, respectively (P = 1.000), while definite ureteric leak occurred in 1 HCV-positive recipient and none of the HCV-negative recipients (P = .389). No CMV or BK virus infection was documented in either group. Two deaths occurred overall, one in each group (P = 1.000).

Table 1: Baseline characteristics

Variable	HCV-positive (n=14)	HCV-negative (n=22)	P value
Age, years	38.71 ± 12.51	37.77 ± 10.84	.819
Male sex	12 (85.7%)	16 (72.7%)	.441
DDRT	8 (57.1%)	15 (68.2%)	.723
Dialysis duration, months	6.93 ± 2.62	6.00 ± 1.90	.263
Tacrolimus level	7.57 ± 1.45	7.77 ± 1.38	.683

Table 2: Renal and transplant outcomes

Outcome	HCV-positive (n=14)	HCV-negative (n=22)	P value
Creatinine at discharge, mg/dL	2.67 ± 1.39	2.51 ± 1.30	.729
Creatinine at 6 months, mg/dL	1.74 ± 0.52	1.84 ± 0.52	.585
Creatinine at 1 year, mg/dL	1.57 ± 0.42	1.55 ± 0.34	.873
eGFR at 1 year, mL/min/1.73 m²	59.71 ± 8.63	60.05 ± 4.94	.898
Delayed graft function	1 (7.1%)	8 (36.4%)	.062
Acute rejection	1 (7.1%)	3 (13.6%)	1.000
Biopsy performed	1 (7.1%)	2 (9.1%)	1.000
Death	1 (7.1%)	1 (4.5%)	1.000

Table 3: Post-transplant complications

Complication	HCV-positive (n=14)	HCV-negative (n=22)	P value
Hematoma (definite)	0 (0.0%)	1 (4.5%)	1.000
Ureteric leak (definite)	1 (7.1%)	0 (0.0%)	.389
Re-exploration	1 (7.1%)	1 (4.5%)	1.000
CMV infection	0 (0.0%)	0 (0.0%)	Not applicable
BK virus infection	0 (0.0%)	0 (0.0%)	Not applicable

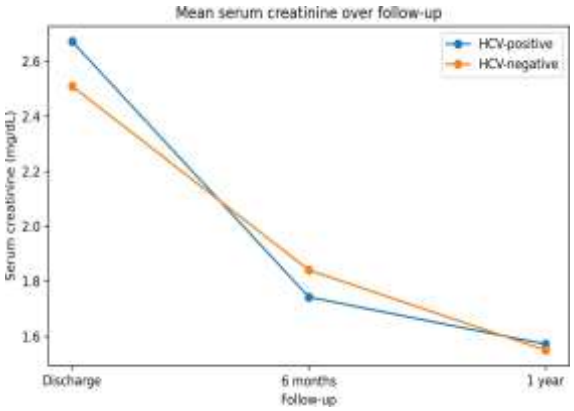

Figure 1: Mean serum creatinine (mg/dL) over follow-up in HCV-positive versus HCV-negative recipients.

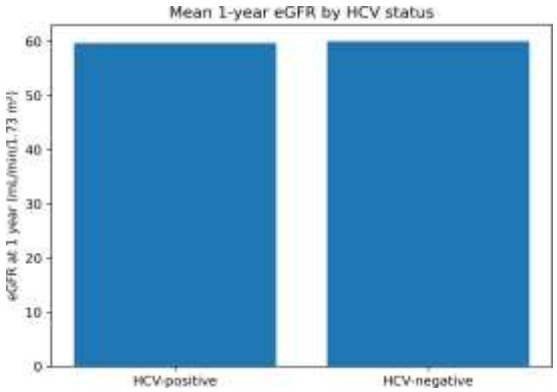

Figure 2: Mean 1-year estimated glomerular filtration rate (eGFR) by HCV status.

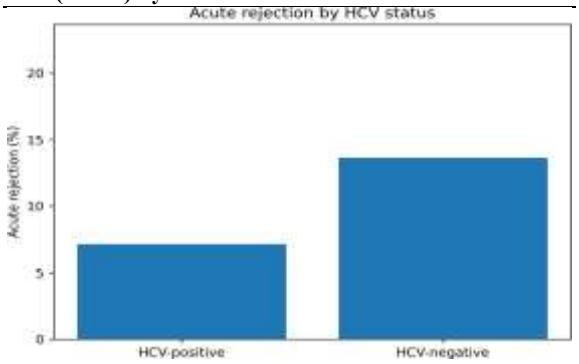

Figure 3: Acute rejection rate (%) by HCV status.

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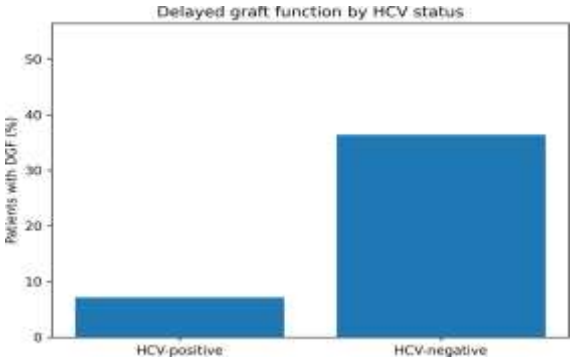

Figure 4: Delayed graft function rate (%) by HCV status.

DISCUSSION

HCV infection has historically been considered an adverse factor in kidney transplantation because of its association with progressive liver disease, cardiovascular morbidity, infection, acute rejection, and reduced patient and graft survival. The introduction of highly effective DAA therapy has substantially altered this scenario and has made transplantation increasingly feasible in appropriately selected HCV-positive recipients (Chute et al., 2018). The present study evaluated whether HCV-positive kidney transplant recipients receiving DAA therapy could achieve outcomes comparable to HCV-negative recipients.

In our study, the two groups were broadly comparable with respect to age and duration of dialysis. The mean age was 38.7 years in the HCV-positive group and 37.8 years in the HCV-negative group. Similarly, the duration of dialysis was not significantly different between the groups. This comparability is important because recipient characteristics and pre-transplant dialysis exposure can influence early graft function and postoperative outcomes.

4.1 Graft Function

The most important finding of the present study was the similarity in renal allograft function between HCV-positive and HCV-negative recipients. Serum creatinine at discharge was 2.67 mg/dL in HCV-positive recipients and 2.51 mg/dL in HCV-negative recipients. At 6 months, creatinine decreased to 1.74 and 1.84 mg/dL, respectively, and at 1 year it was 1.57 and 1.55 mg/dL. None of these differences was statistically significant.

Similarly, the mean eGFR at 1 year was almost identical between the two groups (59.7 vs. 60.0 mL/min/1.73 m²). These findings suggest that, in the setting of effective antiviral treatment, HCV infection itself did not adversely affect intermediate-term renal allograft function in our cohort. The progressive improvement in serum creatinine following transplantation in both groups is also reassuring and indicates satisfactory graft recovery, and the comparable 1-year eGFR further supports the observation that treated HCV-positive recipients can achieve renal functional outcomes similar to those of HCV-negative recipients.

4.2 Delayed Graft Function

DGF occurred in 1 of 14 HCV-positive recipients (7.1%) compared with 8 of 22 HCV-negative recipients (36.4%). Although this difference did not reach statistical significance (P = .062), the numerical difference is noteworthy. The relatively small sample size limits the ability to draw definitive conclusions regarding this observation.

Importantly, there was no evidence in our cohort that HCV-positive status was associated with increased DGF. The slightly higher frequency of DGF in the HCV-negative group may also reflect differences in donor characteristics and induction therapy rather than HCV status itself.

4.3 Acute Rejection

Acute rejection occurred in 1 HCV-positive recipient (7.1%) and 3 HCV-negative recipients (13.6%), with no statistically significant difference. This finding is encouraging because previous concerns regarding HCV infection and transplantation included possible effects on immune activation and rejection.

The low rejection rates observed in both groups may reflect contemporary immunosuppressive protocols and careful postoperative monitoring. The findings suggest that successful management of HCV with DAA therapy does not appear to increase the risk of acute rejection.

4.4 Postoperative Complications and Infections

Postoperative complications were uncommon in both groups. Re-exploration was required in one recipient in each group. In the HCV-negative group, one patient developed a postoperative hematoma requiring intervention, while one patient in the HCV-positive group experienced a ureteric leak. These complications were not associated with a demonstrable adverse effect on overall graft function.

No CMV or BK virus infection was documented during the study follow-up in either group. Although the absence of these infections is favourable, the relatively small sample size and limited duration of follow-up mean that these findings should be interpreted cautiously.

4.5 Patient and Graft Survival

Patient survival was similar between the groups, with one death in each group during follow-up. Most grafts remained functioning at the end of the study period. There was therefore no apparent adverse effect of treated HCV infection on short- to intermediate-term patient or graft outcomes.

These observations are clinically relevant because they support the current concept that HCV positivity should not, by itself, be considered a contraindication to kidney transplantation when effective antiviral therapy is available (American Association for the Study of Liver Diseases–Infectious Diseases Society of America [AASLD-IDSA], n.d.).

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CONCLUSION

In this cohort, HCV-positive kidney transplant recipients treated with DAA therapy demonstrated renal graft function, rejection rates, postoperative complications, and patient outcomes comparable to HCV-negative recipients. The findings support the growing evidence that, in the DAA era, appropriately selected HCV-positive patients can undergo kidney transplantation with favourable outcomes. Larger prospective studies with longer follow-up are required to confirm these findings and determine the long-term impact of HCV eradication on graft and patient survival.

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Competing Interests

Authors have declared that no competing interests exist.

Authors' Contributions

This work was carried out in collaboration among all authors. Author Harry Santhaseelan W conceived and designed the study, supervised data collection and analysis, and drafted and finalized the manuscript. Author D. Mohan Kumar contributed to data collection, patient follow-up, and interpretation of clinical findings, and reviewed the manuscript. Author N. Hariharan contributed to data collection, literature review, and critical revision of the manuscript. All authors read and approved the final manuscript.

Consent

Not applicable. This was a retrospective, anonymized analysis of institutional transplant records; individual patient consent for publication was not required.

Ethical Approval

The authors hereby declare that all procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments. The study was approved by the Institutional Ethics Committee of Coimbatore Medical College Hospital.

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