



Complications of remdesivir in COVID-19 patients with kidney disease: a retrospective cohort study

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ABSTRACT

Introduction: The COVID-19 pandemic has highlighted the vulnerability of patients with chronic kidney disease (CKD) to severe complications from the virus. Remdesivir, an antiviral drug initially developed for Ebola, has emerged as a treatment option for COVID-19, yet its safety and efficacy in patients with kidney disease remain under investigation.

Objectives: This study aims to evaluate the complications associated with remdesivir in COVID-19 patients who have pre-existing kidney conditions.

Patients and Methods: This retrospective cohort study involved 230 COVID-19 patients who were referred to Hasheminejad hospital in Tehran between October 2021 and July 2022, all of whom received a minimum of 100 mg of remdesivir. Participants were categorized based on their history of kidney disease into groups comprising those with CKD, end-stage renal disease (ESRD), and kidney transplant (KT) recipients as well as patients without a history of kidney disease including those with consistently normal kidney function. The study assessed demographic data and laboratory parameters related to liver function, specifically measuring alanine aminotransferase (ALT) and aspartate aminotransferase (AST), along with lactate dehydrogenase (LDH) levels, as well as inflammatory markers, including C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), at both baseline and post-treatment intervals. Data were compared between groups using analytical tests.

Results: Out of 230 included patients, 145 showed no kidney impairment, while 30 had CKD, 35 had undergone KT, and 20 were ESRD. The results indicated that there were no significant differences in liver enzyme levels (including AST and ALT), inflammatory markers (including CRP and ESR), and LDH, from pre- to post-administration of remdesivir between patients with kidney impairment and those without. Additionally, no differences were found among different kidney impairment groups such as CKD, KT, and ESRD. However, LDH and ESR levels were significantly higher in KT patients compared to those without kidney impairment, raising potential concerns for this population.

Conclusion: The findings suggest that remdesivir-related complications concerning liver function, inflammatory markers, and LDH levels did not show significant differences between patients with or without kidney impairment, particular attention should be given to KT recipients due to observed significant increases in LDH and ESR, which may indicate a higher risk of adverse outcomes in this vulnerable population.

Implication for health policy/practice/research/medical education:

In this cohort study, we found that remdesivir does not significantly affect liver function, inflammation level, or lactate dehydrogenase in patients with kidney impairment, suggesting its safety in this population. However, the significantly higher levels of with lactate dehydrogenase (LDH) and erythrocyte sedimentation rate (ESR) observed in kidney transplant patients compared to those without kidney impairment highlight a potential vulnerability that necessitates closer monitoring and tailored management strategies for this group. Overall, remdesivir appears safe regarding liver function and inflammatory responses, the findings warrant further investigation into the implications for kidney transplant patients receiving this antiviral therapy..

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Introduction

COVID-19 began in December 2019 in Wuhan, Hubei province, China, where the first cases were linked to a seafood market. The causative agent, identified as SARS-CoV-2, is a novel coronavirus closely related to bat coronaviruses, indicating zoonotic origins with potential intermediate hosts. This outbreak rapidly escalated into a global health crisis, leading the World Health Organization to declare it a public health emergency of international concern on January 30, 2020, and later a pandemic on March 11, 2020 (1). Until May 2023, the COVID-19 pandemic has resulted in over 676 million confirmed cases and 6.8 million deaths globally (2).

Kidney damage due to COVID-19 has emerged as a significant complication, with studies indicating that acute kidney injury (AKI) occurs in a notable percentage of hospitalized patients, particularly those with severe illness. The mechanisms behind kidney injury may include direct viral invasion of renal epithelial cells, systemic inflammation, and microvascular thrombosis, which can lead to disrupted kidney function. Research has shown that patients with pre-existing chronic kidney disease (CKD) are at higher risk for worse outcomes, and AKI in COVID-19 patients is associated with increased mortality rates (3,4). Additionally, long-term follow-up studies suggest that even after recovery from acute illness, some patients may experience persistent renal impairment, highlighting the need for ongoing monitoring and management of kidney health in COVID-19 survivors (5).

Remdesivir has emerged as a significant antiviral treatment for COVID-19, particularly for hospitalized patients, due to its ability to inhibit the replication of the SARS-CoV-2 virus. Studies indicate that remdesivir can lead to faster recovery times and reduced duration of hospitalization, although its effect on mortality rates remains debated (6,7). A systematic review highlighted that when remdesivir administered in combination with other therapies, such as convalescent plasma, this drug was associated with a significantly lower risk of death in hospitalized patients (8). Furthermore, recent analysis has examined its efficacy across various patient populations, including those with specific health conditions, underscoring the importance of tailoring treatment approaches (9). Despite some concerns regarding the drug's side effects, it continues to be a key component of COVID-19 management protocols worldwide (10).

While remdesivir has demonstrated efficacy in shortening recovery time and reducing mortality in COVID-19 patients, its use in those with renal impairment is complicated by concerns over nephrotoxicity due to the drug's metabolites and its vehicle, particularly in individuals with an estimated glomerular filtration rate (eGFR) below 30 mL/min (11). Previous studies indicated that patients with CKD may experience a higher risk of severe COVID-19 outcomes; however, the safety profile of remdesivir in this population remains uncertain due

to their exclusion from large clinical trials (12). A prior review study also highlighted that despite a high mortality rate among CKD patients with COVID-19, no significant increase in adverse effects was reported from remdesivir administration, suggesting that careful patient selection and monitoring could allow for its use in certain cases (13). However, further research is necessary to establish clear guidelines for safely administering remdesivir in CKD patients (14). This study aimed to evaluate the safety and efficacy of remdesivir in patients with pre-existing kidney disease who are hospitalized due to COVID-19.

Objectives

The objective of this study is to evaluate the complications associated with remdesivir treatment in patients with COVID-19 who have a history of kidney disease. Specifically, the study aims to compare the incidence of liver dysfunction and inflammatory disorders between patients with and without pre-existing kidney conditions. By analyzing clinical outcomes and laboratory data, this research seeks to provide insights into the safety and efficacy of remdesivir in this vulnerable population, eventually informing clinical decision-making and treatment protocols.

Patients and Methods

Study design and participants

The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) Guidelines were used to conduct this retrospective cohort study (15). This study included 230 patients with confirmed SARS-CoV-2 infection, diagnosed through either chest computed tomography (CT) scans or reverse transcription polymerase chain reaction (RT-PCR), who were admitted to the Hasheminejad kidney center between October 2021 and July 2022 and received at least 100 mg of remdesivir. The study analyzed the medical records of these hospitalized COVID-19 patients to evaluate complications, particularly focusing on liver dysfunction and inflammatory disorders. Patients were divided into two groups based on their history of kidney disease; those with CKD defined as a GFR of less than 60 mL/min for more than three months, end-stage renal disease (ESRD) characterized by a GFR of less than 15 mL/min requiring hemodialysis or peritoneal dialysis, and kidney transplant (KT) recipients. Patients without a history of kidney disease included those with consistently normal kidney function, defined as a GFR greater than 60 mL/min.

Inclusion and Exclusion criteria

Inclusion criteria for this study comprised adults aged 18 years and older who had a confirmed diagnosis of COVID-19 based on either a lung CT scan or RT-PCR test and who received at least one dose of remdesivir (100 mg). Patients who were receiving other antiviral treatments concurrently were excluded from the study.

Data collection

Data collection for this study involved gathering detailed demographic, clinical, and laboratory information from participants. Demographic data included age, sex, and comorbidities such as diabetes mellitus (DM), hypertension (HTN), and ischemic heart disease (IHD). Clinical variables focused on the dosage of remdesivir administered to each patient. Laboratory parameters assessed liver function through measurements of alanine aminotransferase (ALT), aspartate aminotransferase (AST), and lactate dehydrogenase (LDH) at both baseline and post-treatment. Additionally, inflammatory markers were evaluated using C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), while renal function was monitored through serum creatinine levels and eGFR.

Outcomes

The primary outcome of this study is to evaluate changes in liver enzymes, inflammatory markers, and LDH before and after remdesivir administration in patients with and without renal impairment. Additionally, the study aims to compare these changes among three subgroups of patients with renal impairment: those with CKD, ESRD, and KT recipients. By analyzing these parameters, the study seeks to identify potential differences in the impact of remdesivir on liver function and inflammation across these patient populations.

Statistical analysis

Data analysis was performed using the Statistical Package for Social Sciences (SPSS) software (IBM Corp, USA) to process the collected information. The normality of the data was evaluated with the Kolmogorov-Smirnov test. To compare qualitative and quantitative variables between the control and case groups, the chi-square or

Fishers' exact tests and one-way ANOVA were utilized. Furthermore, the post hoc least significant difference (LSD) test was applied to assess mean differences among the groups. A *P* value of less than 0.05 was deemed statistically significant, indicating meaningful differences in the analyzed variables.

Results

Among the 230 patients included in the study, 145 did not have kidney impairment, while 30 were diagnosed with CKD, 35 were KT recipients, and 20 had ESRD. The analysis revealed no statistically significant differences in the frequency distribution of key demographic and clinical characteristics, including age, gender, DM, HTN, and IHD, among patients with kidney impairment (CKD, kidney transplantation and ESRD) and those without kidney impairment. These findings suggest comparable baseline profiles across all groups, implying that factors such as age, sex, and common comorbidities did not disproportionately influence the observed outcomes in this cohort (Table 1).

The results indicated that the frequency distribution of laboratory findings, including AST, ALT, LDH, ESR, and CRP, at baseline before remdesivir administration did not show statistically significant differences between patients with kidney impairment (CKD, kidney transplantation and ESRD) and those without kidney impairment. Following remdesivir treatment, the mean values for AST, ALT, ESR, and CRP also remained statistically non-significant across these groups; however, LDH levels were found to be significant. Furthermore, the changes observed in AST, ALT, and CRP from pre- to post-administration of remdesivir did not yield statistically significant differences between the groups, while changes in ESR and LDH were statistically significant (Table 2).

The results demonstrated that the changes in liver

Table 1. Frequency distribution of demographic characteristics among patients without and with kidney impairment across three distinct groups

Variable		Group								P value
		No kidney impairment (n = 145)		CKD (n = 30)		KT (n = 35)		ESRD (n = 20)		
		N	%	N	%	N	%	N	%	
Gender	Male (n= 139)	82	59	20	14.4	23	16.5	14	10.1	0.462*
	Female (n=91)	63	69.2	10	11	12	13.2	6	6.6	
DM	No (n= 171)	112	65.5	19	11.1	25	14.6	15	8.8	0.439*
	Yes (n= 59)	33	55.9	11	18.6	10	16.9	5	8.6	
HTN	No (n= 136)	93	68.4	13	9.6	21	15.4	9	6.6	0.099*
	Yes (n= 94)	52	55.3	17	18.1	14	14.9	11	11.7	
IHD	No (n= 204)	127	62.3	27	13.2	32	15.7	18	8.8	0.969**
	Yes (n= 26)	18	69.3	3	11.5	3	11.5	2	7.7	
Variable		Mean	SD	Mean	SD	Mean	SD	Mean	SD	P value
Age (year)		55.39	16.00	60.83	13.69	53.31	13.34	59.00	16.77	0.176***
Remdesivir dosage (mg)		582.75	156.50	600.0	155.36	622.85	181.63	525.00	209.94	0.196***

CKD, Chronic kidney disease; KT, Kidney transplantation; ESRD, End-stage renal disease; SD, Standard deviation; HTN, Hypertension; DM, Diabetes mellitus; IHD, Ischemic heart diseases.

*Chi-square; **Fishers' exact test; ***ANOVA.

Table 2. Frequency distribution of laboratory findings among patients without and with kidney impairment across three distinct groups

Variable		Group								P value*
		No kidney impairment (n = 145)		CKD (n = 30)		KT (n = 35)		ESRD (n = 20)		
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	
AST (U/L)	Baseline	58.87	47.77	57.26	53.74	61.45	89.21	32.77	25.05	0.451
	After treatment	70.49	65.58	78.81	76.76	85.13	116.54	44.31	24.41	0.419
	Changes	11.62	38.93	21.52	57.34	23.68	72.18	11.54	11.85	0.559
ALT (U/L)	Baseline	58.47	57.88	50.42	46.38	38.75	27.66	28.08	15.15	0.085
	After treatment	72.06	74.55	66.69	59.06	66.58	98.31	38.18	15.59	0.565
	Changes	13.72	37.27	16.42	45.37	27.26	85.08	9.00	12.54	0.570
LDH (U/L)	Baseline	607.79	300.12	577.12	319.19	661.31	418.04	455.38	170.56	0.287
	After treatment	619.69	367.37	772.36	869.20	1309.9	1927.5	843.92	1148.3	0.022
	Changes	11.90	294.65	203.33	697.16	648.65	1719.1	338.54	1150.2	0.012
CRP (mg/L)	Baseline	68.30	51.80	50.25	39.07	56.36	37.40	44.69	30.31	0.305
	After treatment	35.53	47.63	27.39	46.48	22.08	21.41	35.76	21.82	0.627
	Changes	32.77	57.07	22.85	62.95	34.28	31.20	8.93	21.48	0.602
ESR (mm/h)	Baseline	44.13	24.82	72.33	37.31	60.70	35.24	57.25	44.43	0.062
	After treatment	36.00	25.83	57.87	42.06	22.70	21.48	60.20	65.12	0.053
	Changes	8.38	23.39	14.47	28.27	38.00	22.36	2.95	63.56	0.021

CKD, Chronic kidney disease; KT, Kidney transplant; ESRD, End-stage renal disease; SD, Standard deviation; ALT, Alanine aminotransferase; AST, Aspartate aminotransferase; LDH, Lactate dehydrogenase; CRP, C-reactive protein; ESR, Erythrocyte sedimentation rate.

* ANOVA.

enzymes, specifically AST and ALT, as well as LDH levels, from pre- to post-administration of remdesivir did not significantly differ between patients with kidney impairment and those without. Additionally, comparisons among various kidney impairment groups, including CKD, kidney transplantation and ESRD patients, revealed no significant differences in these enzyme levels. However, a notable exception was observed in LDH levels, which were significantly higher in kidney transplantation compared to those without kidney impairment, indicating a potential area of concern for this specific patient population (Table 3).

The results indicated that the changes in inflammatory markers, specifically CRP and ESR, from pre- to post-remdesivir administration did not show significant differences between patients with kidney impairment and those without, nor among the various kidney impairment groups, including CKD, kidney transplantation and ESRD patients. However, a significant difference was noted in ESR levels, with KT patients exhibiting markedly higher values compared to those without kidney impairment, highlighting a potential concern for this particular group (Table 4).

Discussion

Our findings suggest that remdesivir does not significantly impact liver function, inflammation levels, or LDH in patients with kidney impairment, supporting its safety within this population. However, KT patients demonstrated significantly higher LDH and ESR levels compared to individuals without kidney impairment. This highlights a potential vulnerability in KT recipients, emphasizing

the need for closer monitoring and individualized management strategies to mitigate any associated risks during remdesivir treatment. This finding aligns with previous studies that have also reported the drug's safety profile in similar populations; in a study by Chang et al, remdesivir was found to be well-tolerated among hospitalized COVID-19 patients, irrespective of their renal function. They stated that these findings reinforce the recent guidelines recommending the administration of remdesivir in individuals with severe renal impairment, suggesting that its benefits can be safely extended to this high-risk group (16). In another study, Biancalana et al found that remdesivir does not affect eGFR in a group of elderly patients with COVID-19 (17). In a clinical trial by Sise et al, the authors concluded that remdesivir is a safe treatment option for patients with COVID-19 and severe kidney impairment, addressing prior concerns about its use in this high-risk population (18).

In contrast with our study, the study by Chang et al demonstrated that hospitalized COVID-19 patients with severe renal impairment who were treated with remdesivir faced a higher risk of developing AKI, increased hospital mortality, and greater progression of COVID-19 compared to those without severe renal impairment (11). In a retrospective study by Pettit et al, 20 subjects of 135 patients who received remdesivir had GFR of less than 30 mL/min. Serum creatinine elevation was more frequent in groups with kidney dysfunction compared to those without kidney dysfunction. However, it was challenging to ascertain whether the observed elevations in liver functional tests or serum creatinine levels were attributable to the SARS-CoV-2 infection or to remdesivir

Table 3. Comparison analysis of changes observed in Liver enzymes and LDH from pre- to post-administration of remdesivir between patients with kidney impairment (CKD, kidney transplantation and ESRD) and those without kidney impairment

First group		Second group	Mean difference	P value*
Liver enzymes and LDH	AST	CKD	9.89	0.343
		KT	12.05	0.224
		ESRD	0.08	0.995
		KT	2.15	0.865
		ESRD	9.98	0.541
		ESRD	12.13	0.448
	ALT	CKD	2.70	0.805
		KT	13.53	0.186
		ESRD	4.72	0.765
		KT	10.83	0.414
		ESRD	7.42	0.679
		ESRD	18.25	0.297
	LDH	CKD	191.42	0.343
		KT	636.74	0.001
		ESRD	376.63	0.148
		KT	445.32	0.073
		ESRD	185.20	0.537
		ESRD	260.11	0.380

CKD, Chronic kidney disease; KT, Kidney transplant; ESRD, End-stage renal disease; ALT, Alanine aminotransferase; AST, Aspartate aminotransferase; LDH, Lactate dehydrogenase.

* ANOVA and post hoc LSD test.

Table 4. Comparison analysis of changes observed in inflammatory indicators from pre- to post-administration of remdesivir between patients with kidney impairment (CKD, kidney transplantation and ESRD) and those without kidney impairment

First group		Second group	Mean difference	P value*
Inflammatory indicators	CRP	CKD	9.91	0.509
		KT	1.51	0.911
		ESRD	23.84	0.229
		KT	11.43	0.535
		ESRD	13.92	0.551
		ESRD	25.35	0.261
	ESR	CKD	6.09	0.555
		KT	29.62	0.004
		ESRD	11.32	0.439
		KT	23.53	0.069
		ESRD	17.41	0.299
		ESRD	40.95	0.015

CKD, Chronic kidney disease; KT, Kidney transplant; ESRD, End-stage renal disease; CRP, C-reactive protein; ESR, Erythrocyte sedimentation rate.

* ANOVA and post hoc LSD test.

treatment (19).

The findings suggest that remdesivir is a generally safe antiviral treatment for COVID-19 patients with kidney impairment, as no significant complications were observed in this population. This is an important insight, given the initial concerns surrounding the use of remdesivir in individuals with compromised renal function due to its potential nephrotoxic effects. The absence of major adverse effects in this group supports the broader applicability of remdesivir in managing COVID-19 among patients with varying degrees of kidney dysfunction. However, the findings also highlight the need for special caution when using remdesivir in KT

recipients. This subgroup may face unique risks, possibly due to interactions with immunosuppressive therapies or heightened vulnerability to drug-induced nephrotoxicity. These potential risks underscore the importance of individualized risk-benefit assessments and close monitoring when prescribing remdesivir to transplant patients. In conclusion, while remdesivir appears to be a viable treatment option for most COVID-19 patients with kidney impairment, clinicians should exercise heightened vigilance in KT recipients. Further research is warranted to better understand the specific risks and mechanisms affecting this subgroup, as well as to optimize treatment protocols for these vulnerable patients.

Conclusion

The findings of this study provide valuable insights into the safety profile of remdesivir in patients with varying degrees of kidney impairment. Notably, the absence of significant differences in liver enzyme levels (AST and ALT), inflammatory markers (CRP and ESR), and LDH from pre- to post-administration of remdesivir suggests that the drug does not exacerbate liver function or inflammatory responses in this patient population. This is particularly encouraging given the concerns surrounding the use of antiviral therapies in individuals with pre-existing renal conditions. However, the observation that LDH and ESR levels were significantly higher in KT patients compared to those without kidney impairment raises important considerations for clinical practice. This finding indicates a potential vulnerability within the KT population, which may necessitate closer monitoring and tailored management strategies when administering remdesivir. In conclusion, while remdesivir appears to be safe regarding liver enzyme and inflammatory marker levels across different kidney impairment groups, the elevated LDH and ESR in KT patients warrant further investigation. Future studies should focus on understanding the implications of these findings to ensure optimal treatment protocols for COVID-19 patients with kidney disease, particularly those who have undergone transplantation.

Limitations of the study

First of all, the retrospective design inherently limits the ability to establish causality between remdesivir treatment and observed complications, as it relies on previously collected data that may not capture all relevant variables. Second, the study's reliance on medical records may introduce biases related to data completeness and accuracy, particularly regarding laboratory results and patient histories. Additionally, the sample size, while adequate, may not fully represent the broader population of COVID-19 patients with kidney disease, potentially limiting the generalizability of the findings. The exclusion of patients receiving concurrent antiviral treatments could also skew results, as these individuals may have different outcomes compared to those treated solely with remdesivir. These limitations highlight the need for further prospective studies to validate the findings and better understand the implications of remdesivir in this vulnerable patient population.

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Writing—original draft: All authors.

Writing—reviewing and editing: All authors.

Conflicts of interest

The authors declare no conflict of interest.

Ethical issues

The research was conducted in accordance with the Declaration of Helsinki. This study resulted from the research project (No. 22308), with the Ethical code (IR.IUMS.FMD.REC.1401.159; <https://ethics.research.ac.ir/EthicsProposalView.php?id=262908>), approved by the Iran University of Medical Sciences, Tehran, Iran. Prior to any intervention, all participants provided written informed consent. Besides, the authors have ultimately observed ethical issues (including plagiarism, data fabrication, and double publication).

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