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EVALUATION OF CLINICAL OUTCOMES IN CORONAVIRUS DISEASE 2019 PATIENTS TREATED WITH AND WITHOUT REMDESIVIR

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ABSTRACT

Background: The Severe Acute Respiratory Syndrome Coronavirus 2, which triggered the Coronavirus disease 2019 pandemic, has necessitated an immediate and comprehensive assessment of antiviral treatment options. Remdesivir, a broad-spectrum antiviral, was granted emergency use authorization for hospitalized Coronavirus disease 2019 patients; however, its clinical efficacy and safety remain under debate. **Objectives:** To evaluate the effectiveness and safety of Remdesivir compared to Non-Remdesivir regimens in hospitalized patients with Coronavirus Disease 2019, with a specific focus on adverse drug reaction, clinical outcomes, mortality. **Methods:** A six-month retrospective observational study was carried out at a tertiary care hospital in Bengaluru. Medical records of 300 hospitalized Coronavirus Disease 2019 patients were reviewed, of whom 150 received Remdesivir and 150 did not. Clinical parameters and outcomes were analyzed using independent t-tests. **Results:** Patients in the Non-Remdesivir group exhibited significantly lower levels of inflammatory markers including C-reactive protein, D-dimer, and ferritin ($P < 0.05$). They also demonstrated improved Peripheral Capillary Oxygen Saturation, reduced duration of hospital stays, and better radiological improvement on chest X-ray. Importantly, all 20 recorded deaths occurred in the Remdesivir group. Additionally, a higher incidence of adverse drug reactions was observed among Remdesivir recipients. **Conclusion:** Non-

Remdesivir therapy demonstrated more favorable clinical outcomes and a superior safety profile compared to Remdesivir. These findings underscore the need for cautious use of Remdesivir and further large-scale randomized controlled trials.

KEYWORDS: Coronavirus Disease 2019, Remdesivir, Antiviral therapy, Mortality, Efficacy, Adverse drug reactions.

INTRODUCTION

Coronavirus Disease 2019 (COVID-19) is an infectious respiratory condition caused by SARS-CoV-2, a novel coronavirus first reported in Wuhan, China, in December 2019. Its rapid transmission and global Impact led the World Health Organization to classify it as a pandemic.[1,2] SARS-CoV-2, a member of the Coronaviridae family, primarily spreads through respiratory droplets and close contact transmission.[1]

Pathophysiology and Clinical Features: SARS-CoV-2 enters the host cells by engaging angiotensin-converting enzyme 2 (ACE2) causing inflammation and severe respiratory problems.[3] In the most severe cases, this leads to ARDS, systemic inflammatory response syndrome and multi-organ failure. Symptoms can be mild to severe or they may have conducted a mild fever and annoying cough. But others may experience severe difficulty breathing, dangerously low oxygen levels or even neurological problems that require emergency care.[3]

Diagnosis: COVID-19 is largely diagnosed using RT-PCR assays, which detect viral genetic material with high sensitivity. Serological assays and high-resolution computed tomography (HRCT) also support clinical evaluation.[3]

Therapeutic Background–Remdesivir: Originally synthesized for Ebola treatment, Remdesivir is a nucleotide analog that inhibits viral replication.[4] Remdesivir acts by blocking RNA-dependent RNA polymerase, a critical enzyme for viral genome replication. In 2020, the FDA issued emergency authorization for the use of Remdesivir in treating hospitalized patients during the COVID-19 pandemic. However, clinical outcomes have remained inconsistent across different studies, raising questions regarding its efficacy.[5]

Pharmacological Properties: with a pka around 3.5, Remdesivir is consider has an week acid thus affecting its solubility and pharmacokinetic profile, especially in acidic environments such as intracellular spaces.[4]

Adverse Drug Reactions (ADRs): Despite its antiviral activity, Remdesivir has been associated with several adverse events. The most common include:

1. ***Allergic Reactions (including Anaphylaxis):*** Intravenous infusion may trigger hypersensitivity reactions such as hypotension, hypertension, tachycardia, bradycardia, fever, chills, rash, dyspnea, and angioedema.
2. ***Hepatotoxicity:*** Elevated hepatic enzymes (ALT and AST) have been reported, suggesting potential liver injury. Associated symptoms may include fatigue, jaundice, and other signs of hepatic dysfunction.[6]

These clinical outcomes necessitate further investigation for better understand how Remdesivir compares to Non-Remdesivir regimens in both safety outcomes and therapeutic efficacy in the treatment of COVID-19 patients.

OBJECTIVES

The objectives of this study were to

- Examine the efficacy and safety of Remdesivir in hospitalized COVID-19 patients.
- Compare the mortality rates between the Remdesivir and Non-Remdesivir treatment groups.
- Evaluate the incidence and nature of adverse drug reactions (ADRs) associated with Remdesivir therapy.

METHODS

Study Setting and Length: Over the course of six months, this study was carried out at a teaching hospital that provides tertiary care in Bengaluru, India.

Study Design: Hospitalised COVID-19 patients were evaluated according to their treatment plans using a retrospective observational analysis.

Inclusion Criteria

- Hospitalised patients over the age of sixteen, regardless of gender, are eligible to participate.
- RT-PCR testing confirmed the diagnosis of COVID-19
- Patients who were treated without any kind of antiviral medication or who were given Remdesivir

Exclusion Criteria: To maintain safety and reduce confounding clinical variables, women who were pregnant or nursing were not allowed to participate.

Data Gathering Source: The hospital's Medical Records Department (MRD) provided patient-level information, such as demographics, test results, clinical treatment history, and results.

Study Group

- ***Remdesivir Group:*** Individuals receiving Remdesivir while in the hospital
- ***Non-Remdesivir group***:Individuals who were not administered Remdesivir or any other antiviral medication Clinical Results and Assessed Parameters

Efficacy Measures

- Hospital stay duration (measured in days)
- The need for oxygen therapy during the hospital stay
- Improvement in radiologic function as determined by chest X-ray results
- Laboratory markers: Serum concentrations of D-dimer, ferritin, and C-reactive protein (CRP).

Safety inferences

- Rates of in-hospital mortality
- Treatment-related adverse drug reactions (ADRs)

Tools for Statistics Utilized: Independent sample t-tests were used to compare group differences in Quantitative data. Statistical significance was defined as a p-value < 0.05.

Review of Ethics: The Institutional Ethics Committee of St. Philomena's Hospital, Bengaluru, provided ethical clearance.

RESULTS

Demographic Characteristics

A total of 300 hospitalized COVID-19 patients were included in the study, comprising 176 males (59%) and 124 females (41%). Participants were evenly divided into two different groups: 150 patients received Remdesivir (Remdesivir group), while the remaining 150 patients did not receive any antiviral therapy (Non-Remdesivir group).

The highest proportions of patients were observed in the 36–45 and 46–55-year age groups, each accounting for 21% of the study population. This was followed by the 56–65-year group (20.67%) and the 26–35-year group (15%). The younger (16–25 years) and older (≥66 years) age groups comprised smaller percentages, indicating that middle-aged adults were the most commonly affected demographic.

Comparative Clinical Outcomes: A comparative analysis was conducted between the two groups to evaluate key clinical parameters, including duration of hospital stay, levels of inflammatory markers (ferritin, D-dimer, CRP), oxygen saturation at discharge, radiological improvement, mortality, and adverse drug reactions (ADRs).

Length of Hospital Stay: The average stay (in days) of hospitalization was significantly longer in the Remdesivir group (10.77 days) compared to the Non-Remdesivir group (7.72 days), with a statistically significant difference ($p < 0.001$).

Ferritin Levels

- ***Females:*** The Remdesivir group recorded a mean ferritin level of 362.48, significantly exceeding the 158.92 ng/mL observed in the Non-Remdesivir group ($p < 0.001$).
- ***Males:*** Similarly, men receiving Remdesivir had elevated levels (512.92 ng/mL) compared to those not receiving antivirals (330.38 ng/mL), with $p < 0.001$.
- ***D-Dimer (ng/mL):*** A significantly elevated mean D-dimer concentration was found among those given Remdesivir (550.83), compared to the non-antiviral group (370.08) with a p-value of 0.008.

C - reactive protein (CRP): Although the Remdesivir group had a higher average CRP at discharge (18.62 mg/L) versus the Non-Remdesivir cohort (11.61 mg/L), this did not meet the threshold for statistical significance ($p = 0.056$).

Oxygen Saturation at Discharge (SpO_2%): Patients not treated with Remdesivir showed superior oxygenation levels upon discharge, with a mean SpO_2 of 97.49%, markedly above the 94.93% seen in the Remdesivir group ($p < 0.001$).

Radiological Improvements: Chest X-ray findings showed radiological resolution in 94 patients from the Remdesivir group, compared to 114 patients from the Non-Remdesivir group, suggesting better pulmonary recovery among those who did not receive Remdesivir.

Safety findings

Mortality: Out of the 300 patients studied, all 20 recorded deaths occurred in the Remdesivir group, corresponding to a mortality rate of 13.33%. No deaths were reported in the Non-Remdesivir group.

Adverse drug reactions (ADRs): A total of 19 adverse drug reactions were documented in the Remdesivir group. The most frequently observed ADRs included elevated liver enzymes, bradycardia, and acute kidney injury (AKI). In contrast, only 2 ADRs were reported in the Non-Remdesivir group, both of which were mild.

DISCUSSION

Study Population Overview

This retrospective study analyzed 300 RT-PCR-confirmed COVID-19 patients, equally divided into Remdesivir (n=150) and Non-Remdesivir (n=150) groups. A male predominance was observed (59%), which correlates with previous results from Chen N. and Zhang S. et al,[7] who also reported a higher incidence among males during the early outbreak in Wuhan

Age Distribution

The majority of participants were adults with the ages of 36 and 55, with an average age of 49.5 years. Compared to patient populations in Chen N. et al.[7] studies, this age profile is slightly younger.

Co-morbidities Profile

Out of 300 patients, 161 (53.66%) had at least one co-morbidity, while 139 (46.33%) did not have any co-morbidities. The most prevalent conditions were hypertension and type 2 diabetes mellitus; these results align with observations made by Yang J et al. and Bhandari S et al.[8,9] notably, 62% of the study population was not on any regular medication prior to infection.

Ward Admission and Asymptomatic Rate

Most patients (84%) were managed in the medical ward, while 16% required ICU admission. A total of 19 patients (6.33%) were asymptomatic, reinforcing the importance of screening even in the absence of clinical signs.

Clinical Symptomatology

The most frequent clinical **symptoms** were: Fever, Cough, Dyspnea, Fatigue, and Diarrhea

Oxygen Saturation (SpO_2)

The Non-Remdesivir group exhibited significantly higher SpO_2 at discharge (M = 97.49%, SD = 2.61) compared to the Remdesivir group (M = 94.93%, SD = 3.12), (*p*-value < 0.001). This observation supports the result from Motta et al. and Paulo et al, [10] who reported better oxygenation outcomes in patients not treated with Remdesivir.

Inflammatory Marker Profile

D-dimer: The Non-Remdesivir group had lower mean D-dimer levels (370.08 ng/mL) than the Remdesivir group (550.82 ng/mL), with a significant difference (p = 0.008). Similar findings were reported by Poudel et al.[11]

Ferritin: **group who received Non-Remdesivir showed lower ferritin levels** (158.92 ng/mL) than those in the Remdesivir group (362.48 ng/mL) (p < 0.001), Male patients also showed lower levels in the Non-Remdesivir group (330.38 ng/mL) versus Remdesivir (512.91ng/mL)(p<0.001). These values reflect results from studies by Cortes Rojo et al.[12]

CRP

Non-Remdesivir group had lower CRP levels (M = 11.61 mg/L, SD = 23.88) compared to the Remdesivir group (M = 18.61 mg/L, SD = 47.26), supporting data by Wang L. et al.[13]

Hospital Stay Duration

Patients treated without Remdesivir had significantly shorter hospital stays, in line with the observations of Overton et al. and Elliott M.J. et al., who noted prolonged recovery time in Remdesivir recipients.[14]

Radiological Recovery

Radiological Findings: At discharge, more patients showed radiological improvement in the Non-Remdesivir group (114 patients vs. 94), indicating faster pulmonary recovery without Remdesivir therapy.

Mortality Rate

All 20 deaths occurred in the Remdesivir group, indicating a 13.33% mortality rate. This included 17 males and 3 females. No deaths were observed in the Non-Remdesivir group, suggesting a potential association between Remdesivir use and increased mortality, warranting further investigation. Observation of this study nuances the WHO Solidarity Trial findings which questioned Remdesivir's mortality benefit.[15]

Adverse Drug Reactions (ADRs)

A total of 19 ADRs were reported, with 12.66% of the Remdesivir group affected. The most frequent ADRs included: Dexamethasone-induced hyperglycemia, Bradycardia, AKI, Heparin-induced hematuria, Only 2 ADRs were observed in the Non-Remdesivir group, both mild in nature.

CONCLUSION

In this analysis of 300 hospitalized COVID-19 patients, treatments other than Remdesivir were associated with significantly better clinical outcomes, including higher discharge oxygen levels, lower levels of inflammatory biomarkers, shorter length of hospital stay, and lower rates of adverse events. Those who took Remdesivir had a higher chance of death within the study period, encouraging conduct of additional large scale RCTs to systematically evaluate safety and benefit profile it provides.

Conflict of Interest: None.

Funding: None.

Table 1: Table 1. Clinical and demographic comparison of COVID-19 patients receiving Remdesivir versus non-Remdesivir therapy.

Parameter	Remdesivir Group	Non-Remdesivir Group
Study Size	150 patients	150 patients
SpO_2 at Discharge	Less improvement	Significantly improved
D-dimer	Higher	Lower
CRP	Higher	Lower
Ferritin	Higher	Lower
Hospital Stay	Longer	Shorter
Chest X-ray Resolution	94 patients improved	114 patients improved
Mortality	20 deaths (13.3%)	0
Adverse Drug Reactions	19 patients (12.66%)	2 patients (1.33%)

Footnotes: *SpO_2 = peripheral capillary oxygen saturation; D-dimer = D-dimer (a protein fragment); CRP = C-reactive protein; Ferritin = Ferritin (a protein that stores iron).*

Table 2: Adverse drug reactions observed in patients.

Drug	Adverse Drug Reaction	Study Group	No. of Patients	Percentage (%)
Remdesivir	Acute Kidney Injury (AKI)	Remdesivir	2	9.52
Remdesivir	Increased Blood Urea Nitrogen	Remdesivir	4	19.05

Remdesivir	Bradycardia	Remdesivir	4	19.05
Remdesivir	Tachycardia	Remdesivir	1	4.76
Dexamethasone	Elevated GRBS	Remdesivir	7	33.33
Heparin	Hematuria	Remdesivir	1	4.76
Azithromycin	Cold sensation	Non-Remdesivir	1	4.76
Dexamethasone	Tremor	Non-Remdesivir	1	4.76
Total			**21**	**100.00**

Footnotes: Study Group: Indicates whether the adverse drug reaction was observed in patients receiving Remdesivir therapy or Non-Remdesivir therapy. GRBS: Glucose Random Blood Sugar. AKI: Acute Kidney Injury.

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