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Tocilizumab and Remdesivir Versus Remdesivir Alone in Treatment of Hospitalized Patients with Severe COVID-19 Pneumonia

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Abstract

Background: The current SARSCoV-2 epidemic, centred in Hubei Province, China, has spread to many other nations. The WHO Emergency Committee declared a global health emergency on January 30, 2020 due to rising case reporting rates in China and elsewhere. Remdesivir works. Its active counterpart penetrates cells and inhibits viral RdRp, halting viral replication.

Aim of Study: The study aimed to compare between tocilizumab and remdesivir versus remdesivir in hospitalized patients with severe COVID-19 pneumonia.

Subjects and Methods: The study was Interventional, randomized, and double-blinded controlled trial, conducted at ICU Department, El Demerdash Hospitals from Jan. 2023 to June 2023 (Over 6 months) on 100 hospitalized cases with COVID-19 infection.

Results: In all visits there were significant variation amongst the 2 groups regarding Albumin and ALT U/L, WBCs and RBCs, Urea, eGFR, Negative CRP, D-Dimer, Procalcitonin, IL6, and ESR, heart rate and rhythm, NW CPAP Mask, Non-rebreather Mask, CPAP NW, and Simple mask. Regarding Stability of vital signs, and fit for discharge from ICU there was no significant variation among the two groups concerning Blood pressure and Temperature.

Conclusion: In summary, there was significantly decreased oxygen requirement and higher room air consumption, higher improvement of chest condition and lower death, higher discharge from ICU and higher hospital stay till discharge in patients receiving tocilizumab plus remdesivir than patients receiving remdesivir alone.

Key Words: Severe acute respiratory syndrome (SARS) — SARSCoV-2 — Acute respiratory distress syndrome (ARDS).

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Introduction

THE new coronavirus SARSCoV-2 is causing a global outbreak that appears to have begun in Hubei Province, People's Republic of China. Based on rising case notification rates in China and globally, the WHO Emergency Committee declared a global health emergency on January 30,2020 [1].

Individuals infected with SARS-CoV-2 may exhibit mild to severe symptoms, with many others being asymptomatic carriers. Fever (83 percent), cough (82 percent), & shortness of breath (31 percent) are the most frequently reported symptoms [2].

The SARS-CoV-2 virus, which is responsible for the production of COVID-19, has the potential to be treated in a manner comparable to that of other RNA coronaviruses, such as SARS-CoV-1, which is responsible for severe acute respiratory syndrome (SARS), and MERS-CoV, which is responsible for Middle East respiratory syndrome. Coronaviruses infect host cells via fusing with the membranes after following to them [3].

Once inside, the virus employs its RNA-dependent RNA polymerase (RdRp) to subvert the host cell's replication machinery. This non-structural protein is highly conserved across a number of various strains, which makes it a candidate for use as a therapeutic target. For instance, the invention of sofosbuvir, an efficient therapy for hepatitis C infection, was made possible by the utilization of synthetic analogues of nucleosides and nucleotides in order to inhibit RdRp [4].

Remdesivir is an antiviral medication. In addition, its active counterpart penetrates and accumulates in cells, where it blocks viral RdRp and so prevents viral reproduction. There is an enzyme in coronaviruses called exoribonuclease that acts as a "proofreading" enzyme; it finds and fixes mistakes in the RNA sequence, which has the potential to reduce the effects of analogues. Nevertheless, remde-

sivir is able to circumvent this proofreading. Viruses can develop resistance to remdesivir in the laboratory, but the mutant viruses are less infectious **[5].**

The severity of COVID-19 sickness has been linked to IL-6 serum levels, as was demonstrated in multiple studies. Human serum IL-6 concentrations are low in a healthy state (7pg/m1), but they rise rapidly in a sick environment. In critically ill individuals with high IL-6, the Diagnosis and Treatment of Pneumonia triggered by Novel Coronaviruses recommends tocilizumab (TCZ), a humanized monoclonal antibody against the interleukin-6 receptor (IL-6R) **[7].** Tocilizumab was found to be superior to standard therapy in terms of increasing survival, decreasing the requirement for mechanical ventilation & shortening the time of hospital stay **[8].**

This work aimed to compare between tocilizumab and remdesivir versus remdesivir in hospitalized cases with severe COVID-19 pneumonia.

Patients and Methods

This interventional, randomized, and double—blinded controlled trial was conducted in anaesthesia, Intensive Care and Pain Management Department, Faculty of Medicine, Ain Shams University at El Demerdash Hospitals. Over 6 months from Jan. 2023 to June 2023.

Inclusion criteria:

Within 7 days of randomization, individuals had a positive SARS-CoV-2 polymerase chain reaction test result, computed tomography verified pneumonia, and hypoxemia (02 sat <90 percent).

Exclusion criteria:

Individuals with an active bacterial, fungal, viral, or other infection excluding COVID-19; those who have an estimated glomerular filtration rate of below 30mL/min; patients with an alanine aminotransferase or aspartate aminotransferase level above 5 x times the upper limit of normal within 24 hours of screening.

All of the patients would be subjected to the following:

Detailed medical history taking (age- sex- debe-Hating disease history- cardiac illness history- coagulopathy history — COVID-19 affection) and physical examination.

Laboratory and imaging findings:

In COVID-19 pneumonia:

More often than in cases of community-acquired pneumonia, those in hospitals have leukopenia, LDH may be slightly raised, and LFTs are elevated.

A negative result for SARS-2-CoV in a laboratory does not rule out the possibility that the virus is present in the environment. Consolidation or ARDS can develop from ground-glass opacities seen on a chest CT.

About a third of the hospitalized individuals will have to be intubated and placed in the ICU because of ARDS.

Differential diagnosis:

On the basis of clinical criteria alone, COVID-19 cannot be differentiated from other viral respiratory infections, involving the common cold, respiratory syncytial virus, and community-acquired pneumonia.

COVID-19 testing:

The gold standard is still molecular testing (PCR, multiplex panels), although in outpatient settings, the turnaround time is usually 48-72h.

General laboratory tests:

Individuals who are clinically stable and not thought to be at a higher likelihood of decompensation may be permitted to forego tests in the laboratory if they are able to walk safely.

Radiology:

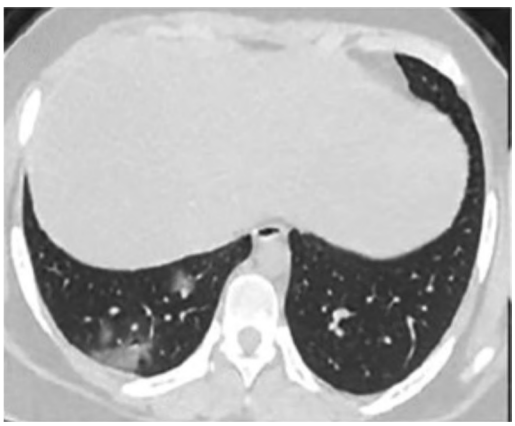

Fig. (1): CT scan of a mildly symptomatic child showing a peripheral ground glass opacity.

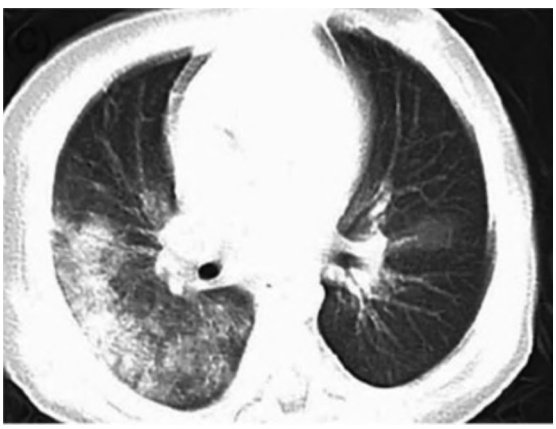

Fig. (2): CT image in a child with severe COVID-19 disease.

Ethical considerations:

Informed consent had be taken from the patients. approval of the Ethical Committee to retrieve data of the patients in the database of Intensive care and Pain Management Department had be sought provided that the patient was not consented preoperatively to include his data in clinical study assuring patient privacy and dignity not stating their personal identity.

Results

The main results were as follows:

In our current study in group A the mean age was 63.64±9.65 years, 60% of cases were female and 40% were males and the mean BMI was 25.42±2.33. While in group B the average age was 63.16±6.14 years, 50% of patients were female and 50% were males and the mean BMI was 25 .28±2.34. In terms of demography, there was not a significant distinction amongst each of the groups.

Our study can be supported by Mohanty et al. **[9].** They sought to determine the efficacy of Remdesivir, Convalescent Plasma, & Tocilizumab in treating severe cases of pneumonia in Covid 19 individuals. According to their findings, they worked with 448 patients whose ages varied from 16 to 91, with a mean age of 51.4% & a standard deviation of 6.4%. Males exceeded females by a 2.7:1 ratio (326 to 122) among the total population.

Concerning vital signs, we found a significant disparity among the examined groups concerning SBP, DBP, P02 & Temperature while there was a significant distinction among the examined groups concerning respiratory rate, SBP and oxygen saturation at first visit and respiratory rate & heart rate at twenty-eighth visit. There was significant distinction among all visits in group A regarding temperature, respiratory rate, heart rate, SBP, DBP, and oxygen saturation. There was significant distinction amongst all visits in group B concerning temperature, heart rate, SBP, DBP & oxygen saturation.

Regarding laboratory investigations, there was significant distinction among the two groups regarding WBCs and RBCs. There was a significant variance amongst the examined groups regarding Hgb, WBCs, RBCs, and Plt at 1st visit & Plt at 28th visit. There was significant distinction among all visits in group A regarding WBCs, RBCs & Plt. There was significant variation amongst all visits in group B concerning Hgb, WBCs, RBCs & Plt.

In concordance with our study Beigel et al. **[10]** Acute kidney injury, diminished eGFR or creatinine clearance, or raised blood creatinine were the most common adverse events (AEs) reported in remdesivir recipients in the ACTT-1 safety population (n=541 & 522 cases treated with remdesivir in addition to placebo, respectively, for 10 days). This was followed by pyrexia (5.0 vs 3.3 percent), hyperglycemia or increased blood glucose level (4.1 vs 3.3 percent); hyperglycemia or increased blood glucose level (4.1 vs 3.3 percent); and increased ALT and/or AST [4.1 vs 5.9 percent], anemia or reduced hemoglobin (7.9 vs 9.0 percent of placebo recipients).

Overreaction of the immune system shown by the production of IL-6, IL-1, IL-2, IL-8, TNFa, and other inflammatory mediators has been observed in individuals with COVID-19, referred to as a cytokine storm or cytokine release syndrome (CRS). Overproduction of cytokines triggers immune cells to produce free radicals, which in turn cause acute respiratory distress syndrome (ARDS), multiple organ failure, and even death. Hyperinflammatory indicators such as interleukin (IL)-6, ferritin, C-reactive protein (CRP), D-dimer, and lactate dehydrogenase are elevated among those with severe COVID-19, suggesting they are experiencing problems related to CRS [11]. Humanized monoclonal IL-6 receptor antagonist tocilizumab (TOCI) has been authorized by the Food and Drug Administration for the treatment of rheumatoid arthritis & giant cell arteritis. The severity and duration of COVID-19 may be minimized with manipulation of proinflammatory IL-6 levels **[12].**

There was a significant distinction among the two groups in Deteriorated, On MV & Room Air with regard to the primary outcome of decreased oxygen need. There was a significant disparity between the two groups in terms of Deterioration, Mortality, and Improvement with respect to the state of the chest. There was no significant disparity among the two groups in terms of the stability of vital indicators (blood pressure, temperature, etc.). While the two groups did have varied RR & HR values, the distinction was significant. There was not a significant distinction between the groups on ICU fitness for release. Discharge, survival, and length of hospital stay were all substantially distinct among both groups.

There was no significant variation amongst the 2 groups regarding demographics data. (Table 1).

Table (1): Demographic data between the investigated groups.

	Group A (N=50)	Group B (N=50)	*P*-value
Age	63.64±9.65	63.16±6.14	0.76729
	67 (38-76)	63 (50-74)	
Sex:			
Female	30 (60%)	25 (50%)	0.31977
Male	20 (40%)	25 (50%)	0.31977
BMI	25.42±233	25.28±2.34	0.76496
	25.5 (21-31)	25 (20-30)	

There was significant disparityamong the 2 groups concerning respiratory rate, SBP, and oxygen saturation. Regarding Oxygen Therapy there was a significant distinction among the both groups concerning NW CPAP Mask, Non-rebreather Mask, CPAP MV, and Simple mask Regarding CBC there was significant variation amongst the two groups concerning Hgb, WBCs, RBCs, and Plt. While there was significant distinctionamong the two groups concerning Bilirubin, AST, ALT, Urea, eGFR, D-Dimer, heart rate and rhythm (Table 2).

Table (2): Data in Frist Visit between the investigated groups.

	Group A (N=50)	Group B (N=50)	*P*- value
Vitals			
Temperature	38.79±1.94 39 (33.3-43.4)	39.07±2.2 38.9 (345-44)	050413
Respiratory rate	2338±4.53 22 (17-35)	2556±1.99 25.5 (22-31)	0.00239*
Heart rate	109.04±10.48 106 (93-133)	108.7±10.44 106 (89-130)	0.87128
SBP	11738±16.97 1195 (88-150)	122.62±7.13 1225 (105-136)	0.04687*
DBP	79.28±9.71 79 (64-103)	78.42±735 80 (63-93)	0.61864
Oxygen saturation	8354±5.11 83 (75-95)	88.74±439 88 (79-100)	<0.0001*
Oxygen Therapy			
NW CPAP Mask	0 (0%)	50 (100%)	
Non-rebreather Mask	15 (30%)	0 (0%)	0.00001*
CPAP NIV	30 (60%)	0 (0%)	<0.0001*
8L Simple mask	5 (10%)	0 (0%)	0.02167*
CBC			
Hgb	12.85±2.15 13.75 (8.7-16.1)	143±1.01 1435 (11.6-16)	0.00004*
WBCs	9.6±1.43 10 (5.4-11)	10.83±0.84 11 (9.4-12.7)	<0.0001*
RBCs	4.1±0.71 4 (3-6)	4.25±051 4 (3-5.4)	0.21847
Plt	247.96±44.08 248.5 (182-344)	26336±21.68 258 (222-321)	0.02894*
ECG			
Rapid Af	5 (10%)	0 (0%)	0.02167*
Sinus Tachycardia	25 (50%)	0 (0%)	<0.0001*
NSR	20 (40%)	50 (100%)	<0.0001*
Chest X-Ray (GGOS)	50 (100%)	50 (100%)	

There was a significant distinction amongst the two groups based on respiratory & cardiac rates. When contrasting the 2 groups, there was a significant distinction in the utilization of oxygen therapy devices like the non-rebreather mask, CPAP NW mask, and simple mask. WBC, RBC, and Plt counts all varied significantly among the two groups on the CBC. When examining Total Proteins, Bilirubin, AST & ALT levels, there was a significant disparity among both groups. There was a significant distinction in Urea, Creatinine & eGFR among the two groups during the kidney function test. D-Dimer levels in the Coagulation profile were significantly different amongst the two groups. When comparing the two groups' ECG results for Rapid Af, Sinus Tachycardia, and NSR, there was a significant variation. The two groups significantly differed concerning CVS, which involves signs and symptoms of venous or arterial thromboembolism. Stroke is triggered by a lack of oxygen and clots, and pulmonary embolism (Table 3).

Table (3): Data in the twenty-eighth Visit between the studied groups.

	Group A (N=50)	Group B (N=50)	*P*- value
Vitals			
Temperature	36.8±2.65 37 (32-44)	37.21±2.2 37 (33-44)	0.40665
Respiratory rate	1956±5.82 165 (14-31)	26.1±1.91 26 (23-32)	<0.0001*
Heart rate	90.88±25.87 78 (65-140)	131.38±7.75 130 (117-150)	<0.0001*
SBP	117±13.37 120 (100-130)	114±10.75 110 (100-130)	058716
DBP	71±738 70 (60-80)	72±6.32 70 (60-80)	0.74863
Oxygen saturation	90.78±4.85 915 (82-101)	90.26±6.18 90 (77-104)	0.64102
OxgenTherap			
Room Air	30 (60%)	0 (0%)	<0.0001*
Invasive MV	15 (30%)	25 (50%)	0.04164*
Nasal Canula 2L	0 (0%)	10 (20%)	0.0007*
Nasal Canula 4L	0 (0%)	10 (20%)	ODOM*
NW Mask CPAP	0 (0%)	5 (10%)	0.02167*
Room Air	5 (10%)	0 (0%)	0.02167*
CBC			
Hgb	13 37±2 .28 14 (8.7-18)	1354±0.93 13.6 (11.6-15.8)	0.63474
WBCs	11.48±4.38 10 (5.8-19)	15.01±438 17 (9-22.1)	0.00011*
RBCs	4.13±052 4.1 (2.8-5)	438±0.48 4.25 (35-5.2)	0.0137*
Plt	247 .76±28 37 249 (200-303)	263.98±47.57 274 (162-337)	0.04101*
ECG			
Controlled Af	1 (2%)	0 (0%)	031977
NSR	25 (50%)	26 (52%)	0.8434
Sinus Tachycardia	24 (48%)	24 (48%)	1
Chest X-Ray			
GGOs	15 (30%)	30 (60%)	0.0023*
Improved	35 (70%)	20 (40%)	0.0025*
Signs and symptoms of venous or arterial thromboembolism			
Ischemic Stroke	5 (10%)	5 (10%)	1
PE	0 (0%)	15 (30%)	0.00001*

There was a significant distinction among the two groups according to Deteriorated, On MV, & Room Air when it came to the need for less oxygen. There was a significant disparity among each of the groups in terms of Deterioration, Death & Improvement according to the state of the chest. There was not a significant distinction among the two groups in accordance with the stability of vital signs (blood pressure, temperature). While the two groups did have different RR & HR values, the distinction was significant. There was not a significant distinction among the two groups depending on Fit for discharge from the ICU. Discharge, survival, and length of hospital stay were all substantially distinct among the two groups (Table 4).

Table (4): Primary Outcomes Data between the investigated groups.

	Group A (N=50)	Group B (N=50)	*P*-value
Decrease Oxygen requirement			
Deteriorated	o (0%)	30 (60%)	<0.0001*
On MV	15 (30%)	0 (0%)	0.00001*
Room Air	35 (70%)	20 (40%)	0.0023*
Improvement of chest condition			
Deteriorated	10 (20%)	15 (30%)	0.00001*
Died	15 (30%)	30 (60%)	<0.0001*
Improved	35 (70%)	20 (40%)	0.0025*
Stability of vital signs			
Blood pressure	114.09±14.67 110 (96-153)	116.87±11.12 116 (100-134)	0.51461
	72.46±4.41 72 (63-80)	71.8±5.32 70 (64-81)	0.65205
RR	14.77±1.54 15 (12-17)	19.1±1.25 19 (16-21)	<0.0001*
Temperature	35.93±1.57 36.1 (32.2-38.7)	36.32±3.09 36 (32-43.4)	0.53963
HR	73.91±4.13 74 (67-84)	95.65±6.05 96.5 (80-103)	<0.0001*
Fit for discharge from ICU			
	15.09±3.23 14 (11-23)	14.85±2.52 14.5 (12-20)	0.77995
Hospital stay till discharge			
	15.8±2.92 16 (9-20)	13.1±1.89 13 (10-16)	0.0005*
Discharge	35 (70%)	20 (40%)	0.0023*
Death	15 (30%)	30 (60%)	0.00043*

Discussion

In line with our findings, Mohanty et al. **[9]** reportedin comparison to the other two modalities, where the mean length of stay was 13.88 days with SD of ±8.71 days in Remdesivir and 13.88 days with a standard variation of 8.73 days for those treated with Convalescent Plasma (CP), the length of stay for individuals treated with Tocilizumab (TCZ) was 14.23 days with an SD of 9.06 days. Individuals administered Remdesivir had a 78% survival rate, those administered with Remdesivir & CP had a 44% survival rate, while those administered with all three had a 13% survival rate.

Tocilizumab reduced overall survival. In contrast to standard treatment, in 2 major open-label platform research, it reduced the requirement for mechanical ventilation & minimized the length of hospital stay.

Remap-Cap Investigators, **[13]** and RECOVERY Collaborative Group, **[14].** Tocilizumab lowered the chance of progression to mechanical ventilation or mortality in the randomized, double-blind, placebo-controlled EMPACTA research among individuals hospitalized with COVID-19 pneumonia who were not receiving ventilatory assistance [in

A prospective meta-analysis by Domingo et al. **[16]** Interleukin-6 antagonists were related to reduced 28-day all-cause mortality in a meta-analysis of 27 randomized trials including over 10,000 individuals hospitalized with COVID-19.

Thiruchelvam et al. [17] revealed that Remdesivir alone for the treatment of hospitalized adults with moderate-to-severe COVID-19 is not currently supported by adequate data. Nevertheless, in patients with pneumonia who require oxygen support, remdesivir may be explored in combination with an anti-inflammatory medication, providing clinical and laboratory data and adverse events are well monitored.

Conclusion:

There was significantly decreased oxygen requirement and higher room air consumption, higher improvement of chest condition and lower death, higher discharge from ICU and higher hospital stay till discharge in patients receiving tocilizumab plus remdesivir than patients receiving remdesivir alone.

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علاج المرضى المصابين بالتهاب رئوى شديد من باستخدام CVOID - 19 دواء الريمديسيفير والتوسيليزوماب مقارنة باستخدام دواء الريمديسيفير فقط

انتشر التفشى لفيروس كرونا الجديد SARSCoV-2 فى منطقة هوبى بجمهورية الصين الشعبيه إلى العديد من البلدان الاخرى فى ٣٠ كانون الثانى (يناير ٢٠٢٠) حيث اعلنت لجنة الطوارئ التابعه لمنظمة الصحه العالميه حالة طوارئ صحيه عالميه بناء على معدلات الأخطار المتزايده فى المواقع الصينيه والدوليه

يوصى باستخدام عقار توسيليزوماب وهو مضاد لمستقبلات IL-6 فى المرضى المصابين بالالتهاب الرئوى الحاد المصاحب لفيروس كورونا المستجد وثبت لديهم ارتفاع حاد فى مستوى IL-6.

ثبتت نسبة التحسن للمرضى باستخدام عقار (توسيليزوماب) متمثله فى البقاء علي قيد الحياة، وتقليل الاحتياج لجهاز التنفس الصناعى للمريض، وبالتالى قصر مدة الاقامه بالمستشفى مقارنة بالرعايه القياسيه .

الهدف من الدراسة: هدفت الدراسه إلى المقارنة بين استخدام عقارى (توسيليزوماب + ريمديسفير) واستخدام عقار (ريمديسيفير) فقط بالاضافه إلى علاجهم وفقا لبروتوكولات علاج المرضى المصابين بالتهاب رئوى شديد مصاحب لفيروس كورونا المستجد -١٩ وتم حجزهم بالمستشفى.

كانت الدراسة تدخلية، عشوائية، مزدوجة التعمية ذات شواهد، أجريت في قسم العناية المركزة فى مستشفيات الدمرداش من يناير ٢٠٢٣ إلى يونيو ٢٠٢٣ (أكثر من ٦ أشهر) على ١٠٠ مريض المستشفى مصابين بعدوى التهاب رئوى شديد بسبب فيروس كورونا المستجد.

أظهرت النتائج الرئيسية للدراسة مايلى:

١. فيما يتعلق بتحسن حالة الصدر كان هناك فرق ذو دلالة إحصائية بين المجموعتين فيما يتعلق بالتدهور والوفاة والتحسن.
٢. فيما يتعلق بصلاحية الخروج من وحدة العناية المركزة كان هناك فرق ذو دلالة إحصائية بين المجموعتين فيما يتعلق بالبقاء فى المستشفى حتى الخروج، والخروج، والوفاة.