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Original Article

Comparative Analysis of Clinical Outcomes of COVID-19 Patients With and Without Antibiotic Administration: A Randomized Clinical Trial

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Abstract

Background and aims: Antibiotics are essential for confirmed bacterial infections associated with coronavirus disease 2019 (COVID-19). However, their efficacy in improving the clinical course of the disease without a concomitant bacterial infection has not been established. Thus, this study aimed to evaluate the effectiveness of antibiotic treatment on the clinical course of COVID-19, thereby increasing the credible evidence produced by randomized clinical trials on the efficacy of antibiotics for managing COVID-19.

Methods: In general, 90 patients with COVID-19 were randomly assigned to either an intervention or the control group. Cephalosporins and fluoroquinolones were administered for a period of five days. Laboratory factors and the disease course were determined for both groups. The data were analyzed using SPSS 26.

Results: Intragroup comparisons of the mean erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) in both groups were significantly lower on day 7 than on day 1 ($P<0.001$), but the mean ferritin did not change significantly ($P=0.071$). However, the mean oxygen saturation, respiration rate, and fever in both groups improved significantly by days 7 and 14 compared to day 1 ($P<0.001$). In the intergroup comparison, changes in the oxygen saturation, ferritin, CRP, and ESR were not significantly different between groups. Likewise, the prevalence of fever and respiratory rate did not significantly differ between groups on days 1, 7, and 14.

Conclusion: Antibiotics had no significant effect on the clinical course and laboratory parameters of patients with COVID-19. Accordingly, they are not recommended except in cases of concomitant bacterial infections.

Keywords: COVID-19, Coronavirus, Antibiotic, Remdesivir, Erythrocyte sedimentation rate, C-Reactive protein

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Introduction

Coronavirus disease 2019 (COVID-19) is a public health problem, and there is a decreasing trend in life expectancy. The mortality rate continues to increase worldwide (1). Antimicrobials are being used more frequently in the treatment and prevention of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral infections (2). A small proportion of COVID-19 pneumonia cases have been associated with bacterial infection, the majority of which are safely and effectively treated with antibiotics (3).

Antibiotics are frequently prescribed to combat bacterial infections; however, recent laboratory research has shown that certain antibiotics, such as fluoroquinolones and macrolides, exhibit antiviral activities in addition to their antibiotic activities and may be beneficial in treating viral infections (4, 5). Fluoroquinolones inhibit Zika, hepatitis, and rhinoviruses, among others (6, 7). This activity appears to be retained in SARS-CoV-2, indicating that it could be used to treat COVID-19 in patients (4). Moreover, azithromycin, ceftriaxone, amoxicillin, ciprofloxacin, ceftazidime, cefepime, vancomycin, and other antibiotics have been suggested for the treatment of COVID-19, with most directives recommending direct and empirical antibiotic treatment (3).

Co-bacterial and fungal infections were detected in only 8% of COVID-19 patients in a recent study; however, 72% of the patients received antibiotic treatment (8). Empirical antibiotic use in COVID-19 patients can increase the likelihood of bacterial resistance, thereby imposing additional expenses on patients and the healthcare system (9, 10). Antibiotic resistance is a serious issue that has been overlooked for far too long and demands immediate attention. According to the World Health Organization, antibiotic treatment or prophylaxis is not recommended in patients with mild to moderate COVID-19, except in exceptional circumstances (2, 11). The current study seeks to assess the effectiveness of antibiotic treatment on

the clinical course of COVID-19 in order to increase the credible evidence created by randomized clinical studies on the efficacy of antibiotics for COVID-19 management.

Materials and Methods

Trial Design

This double-blind, parallel-group, randomized controlled trial was conducted in 2021 at Hajar Hospital in Shahrekord, Iran, to evaluate the efficacy of antibiotics in COVID-19 patients undergoing standard treatment. Participants were randomly allocated to either the control group or the intervention group in a 1:1 ratio using permuted block randomization with sealed, opaque envelopes to ensure allocation concealment (Figure 1).

Inclusion Criteria

Eligible participants were adults aged 18 years or older who had a confirmed diagnosis of COVID-19 via a positive real-time polymerase chain reaction test, had peripheral oxygen saturation (SpO_2) > 93% on room air, and had moderate pulmonary involvement, defined as < 50% involvement on chest computed tomography scan without signs of respiratory failure. In addition, the participants were included in the study if they had no clinical or laboratory evidence of bacterial infection, as indicated by a procalcitonin (PCT) level < 0.1 ng/mL.

Exclusion Criteria

Exclusion criteria included refusal to provide informed consent (1), withdrawal from the study at any point (2), development of hypersensitivity or adverse effects to the administered medications, and (4) requirement for antibiotics based on clinical judgment or elevated PCT after enrollment. Moreover, patients were excluded from the investigation if they suffered from severe/critical COVID-19 or immunosuppression or were currently receiving antibiotic therapy.

Sample Size

The sample size was determined using a formula designed for comparing the means between the two groups. The sample size was determined to be 45 individuals per group based on previous research and comparisons of pharmaceutical interventions with the standard treatment for COVID-19, as well as S1: 8.19, S2: 3.47, μL: 6.3, μ2: 2.37, α = 0.05, β = 0.2, and a 10% dropout rate (12). The following sample size formula was utilized for this study:

$$n = \frac{\left(z1-\frac{\alpha}{2}+z1-\beta\right)^2\left[S_1^2+S_2^2\right]}{\left[\mu 1-\mu 2\right]^2}$$

where Z_1-α/2 = 1.96 (for a 95% confidence level), and

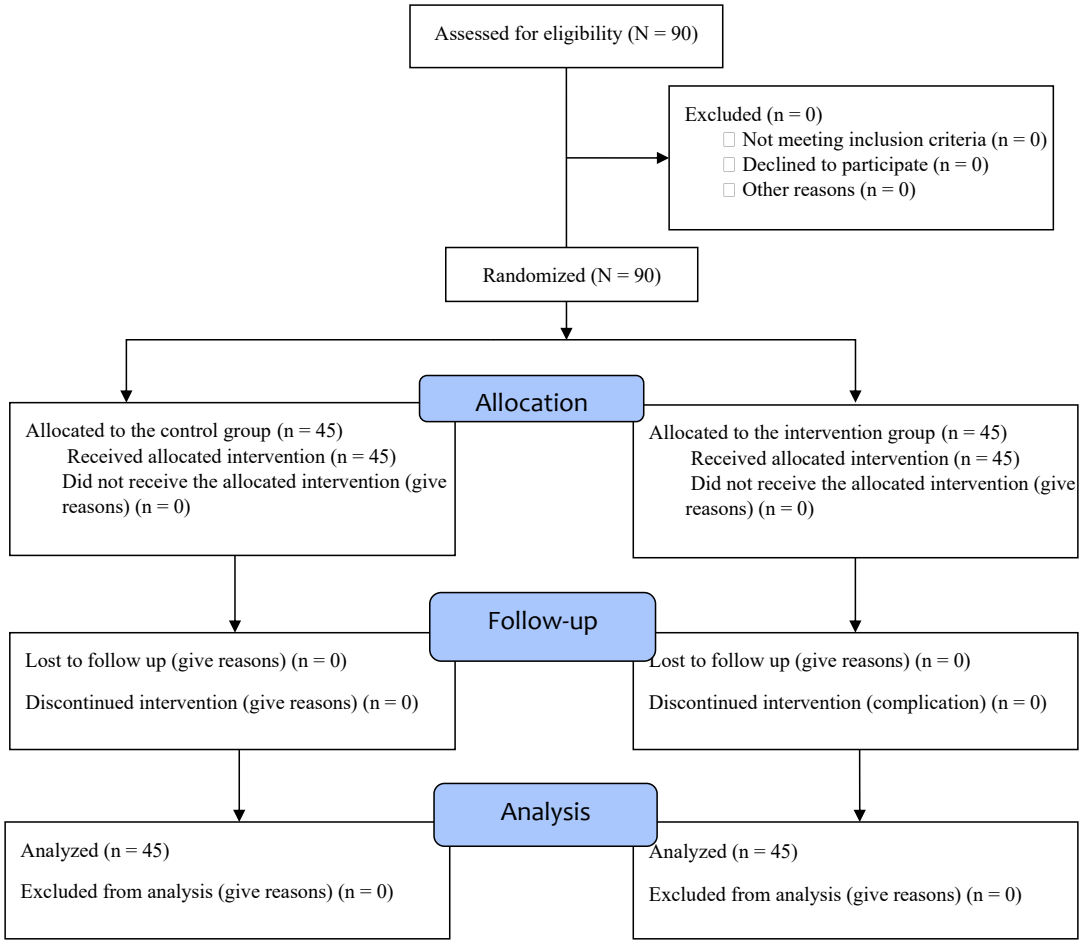

Figure 1. CONSORT Flow Diagram of the Study Population
Note. CONSORT: Consolidated Standards of Reporting Trials

Z_1-β = 0.84 (for 80% power). Further,

σ_1 and σ_2 are estimated standard deviations from prior data. Furthermore, μ_1 and μ_2 denote the expected mean differences in the primary outcome (C-reactive protein [CRP] reduction). An additional 10% was added to account for potential dropouts.

Randomization and Allocation

Participants were randomly allocated to the intervention or control group using a computer-generated random sequence. Allocation was performed using sequentially numbered, opaque, sealed envelopes prepared by an independent staff member not involved in the recruitment or analysis process.

Intervention

The patient was registered in one of the groups based on the option enclosed in the envelope. The control group was given the standard treatment alone. In contrast, the intervention group received the standard therapy in combination with antibiotics. Cephalosporins (cefepime 1 g every 12 hours or ceftriaxone 1 g every 12 hours) and fluoroquinolones (ciprofloxacin 400 mg every 12 hours or levofloxacin 750 mg daily) were administered over 5 days (13, 14). It should be noted that drug selection was based on availability and physician discretion. Antibiotic administration was initiated only after confirming PCT negativity to exclude bacterial coinfection. Moreover, medication adherence was monitored through nursing records and patient logs.

The standard medication regimen was the administration of remdesivir for 5 days. According to the national protocol, 200 mg of remdesivir was prescribed on day 1, followed by 100 mg administered on days 2–5 (15). On day 1, the PCT was checked, and patients who tested positive and required antibiotics were excluded from the study. Conversely, patients who tested negative were included in the study. Erythrocyte sedimentation rate (ESR), CRP, ferritin, oxygen saturation levels, temperature, and respiration rate were measured before and after the intervention. The oxygen saturation levels, temperatures, respiratory rates, and mortality rates of patients in both groups were evaluated after 14 days. Additionally, the respiratory rate was manually measured at rest by trained nursing staff, and temperature was recorded using a standardized digital thermometer.

Blinding

This was a double-masked trial. Participants, healthcare providers, and outcome assessors were blinded to group assignments. In addition, antibiotics and a placebo were packaged in identical containers by a pharmacist who was not involved in the trial.

Statistical Analysis

SPSS software (version 26) was used to analyze the data. The Friedman test was employed to compare ordinal variables in dependent groups with more than two replicates. Moreover, the Wilcoxon test was utilized to compare ordinal variables in dependent groups with two replicates. Likewise, the Cochran's Q and McNemar's tests were applied to compare nominal variables in dependent groups with more than two and two replications, respectively. Further, ordinal variables between independent groups and nominal variables between independent groups were compared using the Mann-Whitney and chi-square tests, respectively. Eventually, the independent t-test was used to compare the mean of a scale variable with a normal distribution between independent groups, and a level of $P < 0.05$ was considered statistically significant.

Results

Overall, 90 patients with COVID-19 who had negative procalcitonin test results were treated and evaluated in two groups of 45 individuals: a control group (remdesivir) and an intervention group (remdesivir + antibiotic). The chi-square test results revealed no significant differences between the two groups ($P = 0.191$). Specifically, 31 (68.9%) of the 45 patients in the control group and 26 (57.8%) of the 45 patients in the intervention group were male. The mean age between groups was not significantly different ($P = 0.191$) as determined by the independent t-test. Similarly, the mean PCT in the control and intervention groups was 0.7, with no significant difference ($P = 0.888$), as determined by the Mann-Whitney test (Table 1).

The Wilcoxon test for intragroup comparison revealed that the mean ferritin levels on days 1 and 7 were not significantly different in the control group ($P = 0.074$). However, the mean CRP and ESR levels on days 1 and 7 demonstrated a significant difference ($P < 0.001$). Based on the results, the mean ferritin level in the intervention group did not differ significantly on days 1 and 7 ($P = 0.910$). Contrarily, the CRP and ESR levels were significantly different on these days ($P < 0.001$).

On different days, the Friedman test for intragroup comparison of oxygen saturation indicated a significant difference between the control and intervention groups ($P < 0.001$). In addition, the oxygen saturation on days 1 and 7 ($P < 0.001$), days 1 and 14 ($P < 0.001$), and days 7 and 14 ($P < 0.001$) showed significant differences between the control and intervention groups, as determined by the Wilcoxon test (Table 2).

The Mann-Whitney test for intergroup comparison of

Table 1. Intergroup Comparison of Gender Frequency Distribution, Mean Age, and PCT

Variables		Groups		*P*-Value
		Control	Intervention	
Gender	Male, n (%)	31 (68.9)	26 (57.8)	0.191
	Female, n (%)	14 (31.1)	19 (42.2)	
Age (mean ± SD)		55.18 ± 15.11	54.56 ± 15.98	0.850
PCT (mean ± SD)		0.7 ± 0.6	0.7 ± 0.5	0.888

Note. PCT: Procalcitonin; SD: Standard deviation.

quantitative variables confirmed that oxygen saturation, ferritin, CRP, and ESR did not differ significantly between groups (Table 3).

Based on Cochran's Q test results regarding the intragroup comparison of respiratory rate and fever, the respiratory rate and fever significantly differed within groups on days 1, 7, and 14 ($P<0.001$). Similarly, the frequency of fever and tachypnea on day 1 ($P<0.001$) was significantly different from that on days 7 ($P<0.001$) and 14 ($P<0.001$) in the control group, according to McNemar's test. Additionally, the frequency of fever and tachypnea in the intervention group on day 1 significantly varied from that on days 7 ($P<0.001$) and 14 ($P<0.001$) (Table 4).

According to the chi-square test, fever ($P=0.500$) and respiratory rates on day 1 ($P=0.095$) were not significantly different between groups. In addition, neither group of patients showed symptoms of fever on days 1 and 14. Only one patient in the intervention group and none of the control group patients had tachypnea on day 7. Moreover, no one in either group experienced tachypnea on day 14 (Table 5).

Discussion

The ninety COVID-19 patients admitted to Hajar Hospital with negative procalcitonin tests were divided into the control (remdesivir) and intervention (remdesivir + antibiotic) groups (n = 45 per group) to collect data on the clinical course of the disease. Laboratory data from the two groups were collected before the intervention and on days 7 and 14. The findings revealed that the mean CRPs and ESRs on day 7 in both groups were significantly better than on day 1, as were the oxygen saturation levels, respiration rates, and fever on days 7 and 14. However, there were no significant differences in the mean ferritin levels between groups.

Intergroup examination demonstrated that the differences in mean oxygen saturation, ferritin, CRP, and ESR between groups were nearly identical and not statistically significant. Furthermore, the frequency of fever and tachypnea on days 1, 7, and 14 was similar in both groups, with no significant differences. Based on the findings, all patients recovered. Overall, the control and intervention groups had the same clinical outcomes and laboratory findings. Accordingly, antibiotic treatment had

Table 2. Intragroup Comparison of Mean Ferritin, CRP, ESR, and O_{2Sat}

Variables	Groups	Day 1 (Mean ± SD)	Day 7 (Mean ± SD)	Day 14 (Mean ± SD)	*P* value
Ferritin	Control	537.98 ± 492.49	642.91 ± 518.74	-	0.074
	Intervention	623.55± 577.87	618.36 ± 444.44	-	0.910
CRP	Control	58.28 ± 36.51	37.28 ± 36.84	-	0.001
	Intervention	66.71 ± 28.53	27.45 ± 24.07	-	0.001
ESR	Control	33.62 ± 23.09	14.62 ± 12.94	-	0.001
	Intervention	33.49 ± 17.88	19.91 ± 15.89	-	0.001
O_{2Sat}	Control	86.07 ± 5.07	92.58 ± 2.48	95.42 ± 1.61	0.001
	Intervention	86.56 ± 4.66	92.51 ± 2.49	95.29 ± 2.86	0.001

Note. CRP: C-reactive protein; ESR: Erythrocyte sedimentation rate; O_{2Sat}: Oxygen saturation; SD: Standard deviation.

Table 3. Intergroup Comparison of Mean Differences in Oxygen Saturation, Ferritin, CRP, and ESR

Variable	Control (Mean ± SD)	Intervention (Mean ± SD)	*P* value
O_{2Sat} mean difference (day 1 to day 7)	6.51 ± 3.09	5.95 ± 2.71	0.471
O_{2Sat} mean difference (day 1 to day 14)	9.35 ± 4.08	8.73 ± 3.4	0.535
O_{2Sat} mean difference (day 7 to day 14)	2.84 ± 1.41	2.77 ± 1.14	0.942
Ferritin mean difference	401.43 ± 43.401	412.58 ± 59.51	0.071
CRP mean difference	62.93 ± 29.91	53.71 ± 42.64	0.262
ESR mean difference	19.40 ± 19.00	15.09 ± 13.57	0.406

Note. CRP: C-reactive protein; ESR: Erythrocyte sedimentation rate; O_{2Sat}: Oxygen saturation; SD: Standard deviation.

Table 4. Comparison of the intragroup frequency distribution of fever and respiratory rate on Days 1, 7, and 14

Group		Respiratory Rate		*P*-Value	Fever		*P* value
		Less Than 20 Per Minute	More Than 20 Per Minute		Yes	No	
Control	Day 1	25	20	0.001	25	20	0.001
	Day 7	45	0		45	0	
	Day 14	45	0		45	0	
Intervention	Day 1	32	13	0.001	26	19	0.001
	Day 7	44	1		45	0	
	Day 14	45	0		45	0	

Table 5. Intergroup Comparison of Fever Frequency and Respiratory Rate at Different Times

Variable		Control n (%)	Intervention n (%)	*P* value
Fever on day 1	No	25 (55.6)	26 (57.8)	0.500
	Yes	20 (44.4)	19 (42.2)	
Fever on day 7	No	45 (100)	45 (100)	-
	Yes	0 (0)	0 (0)	
Fever on day 14	No	45 (100)	45 (100)	-
	Yes	0 (0)	0 (0)	
Respiratory rate on day 1	Less than 20 per minute	25 (55.6)	32 (71.1)	0.095
	More than 20 per minute	20 (44.4)	13 (28.9)	
Respiratory rate on day 7	Less than 20 per minute	45 (100)	44 (97.8)	0.500
	More than 20 per minute	0 (0)	1 (2.2)	
Respiratory rate on day 14	Less than 20 per minute	45 (100)	45 (100)	-
	More than 20 per minute	0 (0)	0 (0)	

no noticeable effect on the clinical course or laboratory parameters of the COVID-19 patients, and it is not recommended unless a concomitant bacterial infection is present.

Several retrospective and descriptive studies have so far assessed the effectiveness of antibiotic treatment in COVID-19 patients, yielding similar results. For example, a retrospective cohort analysis was conducted by Yin et al (16) on 1,613 non-severe COVID-19 patients without signs of bacterial infection, comparing two groups treated with antibiotics and a control group. Although severe illness, hospital stays of more than 15 days and secondary infection were all related to the early use of antibiotics, they did not affect mortality. Antibiotic therapy was associated with more negative outcomes in previous trials than in the current study. This was likely due to population differences and the specific antibiotic prescribed.

Liu et al (2), in a trial of 1,123 patients with COVID-19, found that treatment with moxifloxacin and intravenous meropenem was related to increased mortality in patients suspected of having bacterial infections. Oral antibiotics, on the other hand, reduced mortality in this group. Furthermore, the use of moxifloxacin and meropenem was linked to an increased risk of death in individuals who had no evidence of bacterial infection. Thus, patients with a suspected bacterial infection were more likely to have poor clinical outcomes than those without a suspected bacterial infection. Hence, antibiotics may not provide the intended results when used empirically.

Sivapalan et al (17) conducted a placebo-controlled, double-masked, randomized trial on COVID-19 patients, showing that a 15-day intervention with azithromycin, combined with routine treatment, had no significant effect on survival and duration of hospitalization compared to routine treatment alone, which aligns with our results. Additionally, Oldenburg et al (18) reported that 263 outpatient COVID-19 patients treated with a single dose of oral azithromycin (2.5 g) compared to a placebo demonstrated no significant difference in complete symptom relief by day 14 after treatment.

Moreover, Popp et al assessed the effectiveness of antibiotics in treating COVID-19 in adults and concluded that the use of azithromycin in hospitalized COVID-19 patients did not reduce the risk of death. Furthermore, based on evidence of moderate certainty, azithromycin was unlikely to provide clinical improvement or prevent deterioration in patients with mild to severe illness in an inpatient setting despite its proposed antiviral and anti-inflammatory properties. However, the available evidence remains insufficient to determine whether azithromycin offers any benefit for COVID-19 patients treated in an outpatient setting (19).

Wang et al (20) observed that, despite the lack of etiological evidence, the rate of antibiotic use in COVID-19 patients ranged from 13.2% to 100% in adults based on the findings of 33 descriptive cross-sectional studies. Fluoroquinolones, cephalosporins, and macrolides were the most commonly used antibiotics for adults. Studies have shown no evidence against recommending antibiotics for COVID-19 patients without a concomitant bacterial infection. Overall, the findings of previous research support those of the current study, indicating that antibiotic treatment may be ineffective or even harmful for COVID-19 patients who do not exhibit signs of bacterial infection. Differences in study designs (trial or retrospective), type of antibiotic used, dose of the drug, course of treatment, and severity of the disease in previous studies imply that more research with larger sample sizes, in the form of randomized controlled clinical trials, is recommended in this regard.

Conclusion

Overall, it was revealed that antibiotic treatment was ineffective in improving the clinical course and laboratory parameters of patients with COVID-19. One of the study's merits is that it was designed as a controlled, double-masked clinical trial, which allowed for a more accurate comparison of the two groups treated with and without antibiotics. Nonetheless, the small sample size was a limitation of the study. Thus, it is recommended that

more studies with larger sample sizes be undertaken in this respect.

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Authors' Contribution

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Competing Interests

The authors declare that there is no conflict of interests to disclose.

Ethical Approval

The study protocol was approved by the Ethics Committee of Shahrekord University of Medical Sciences (IR.SKUMS.REC.1400.181). This study was also registered in the Iranian Registry of Clinical Trials (IRCT20210510051248N1).

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