IMPACT OF COLCHICINE ON THE CLINICAL OUTCOME OF COVID-19

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ABSTRACT:

Background: *Because of the emergence of the pandemic of SARS-Cov2 infection and the Global burden of COVID-19 on the worldwide healthcare systems, it became mandatory for all researchers to search for better preventive as well treatment strategies.*

Aim of the Work*: The aim of the work is to study the effects of colchicine on the COVID-19 patients' clinical outcomes and the inflammatory markers during the disease.*

Material and Methods: *This comparative, randomized controlled study has been conducted on patients confirmed to have COVID-19 attending Ain Shams Isolation hospital from Feb-2021 and May-2021. The institutional review board of Ain Shams University's research ethical committee approved the study. A total of 260 participants were randomized with 130 assigned to each group as follows: The Study Group (colchicine group) (n=130): included patients who received COVID-19 treatment protocol plus colchicine according to the study protocol. The Control Group (n=130): included patients who received COVID-19 treatment protocol only without colchicine.*

Results*: Both groups were comparable regarding age, BMI, and gender. Females constituted 58.1% & 56.0% of cases in the colchicine group & the control group, respectively. At presentation, as regards the severity, both groups are comparable (p = 0.553). In day 14, the improvement in the clinical status in the colchicine group 0.64 (0.96) is significantly (p-value = 0.002) higher than in the control group 0.28 (0.99).*

Conclusion*: The beneficial effect of colchicine in COVID-19 cases is self-evident for both the clinical status and laboratory evaluation*

Keywords: *Cochicine, COVID-19, clinical status, inflammatory markers.*

INTRODUCTION:

Approximately 457 million people have been diagnosed with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), and around two million people have died from this deadly disease worldwide [(1)]. The pulmonary symptoms associated with SARS-CoV-2 vary from mild respiratory symptoms to severe respiratory failure. Of those infected with SARS-CoV-2, 40% will progress to acute respiratory distress syndrome (ARDS)[(2)].

The therapeutic use of colchicine has been well documented in gout and other diseases, including pericarditis, primary biliary cirrhosis, relapsing polychondritis, scleroderma, amyloidosis, idiopathic retro-peritoneal fibrosis, and other inflammatory and fibrotic conditions[(3-5).]

Animal studies also showed that colchicine reduces all the compounds that

intervene to intensify the inflammatory process like reactive oxygen species (ROS), nitric oxide (NO), and others[6]. Thus, colchicine can minimize such damage using different paths. Besides, colchicine affects NLRP3 and prevents the activation of IL-6 and other interleukins (IL-18 & IL-1β); thus, it can have a role in acute respiratory distress syndrome/acute lung injury (ARDS/ALI). Consequently, it appears to play a vital role in reducing and controlling the cytokines storm[7&8]. Therefore, according to colchicine's anti-inflammatory effects, it may significantly reduce the symptoms, course, and mortality rate caused by the new coronavirus disease. In COVID19 cases, colchicine was used by Deftereos SG et al. (2020), where they assessed its impact on the inflammatory biomarkers and clinical outcomes[9].

AIM OF THE WORK:

The work aims to study the effects of colchicine on the coronavirus disease 2019 patients' clinical outcomes and the level of inflammatory markers.

MATERIAL AND METHODS:

The current randomized controlled trial (RCT) was conducted on patients confirmed to have COVID-19 by PCR attending Ain Shams Isolation hospital from Feb-2021 and May-2021. The institutional review board of Ain Shams University's research ethical committee approved the study. A total of 312 patients with confirmed COVID-19 were asked to participate in this study. Twenty-one subjects refused to participate, and 31 subjects were excluded before randomization because they did not meet the inclusion criteria, leaving 260 participants for randomization with 130 assigned to each group as follows: The Study Group (colchicine group) (n=130): included patients who received COVID-19 treatment protocol plus colchicine according to the study protocol.

The Control Group (n=130): included patients who received COVID-19 treatment protocol without colchicine. Six subjects were excluded after randomization and before any intervention.

We invited all eligible patients aged 18 years or more who came to the center to participate. For inclusion in the study, all of the following criteria were to be fulfilled; age 18 years or more, male or female, confirmed to have COVID-19 clinically, radiologically, and PCR.

Patients with a history of hypersensitivity to colchicine, pregnant or breastfeeding women, patients with severe renal impairment (creatinine clearance (CCL) <30 mL / min), patients with severe hepatic impairment (AST or ALT> 5 times the normal limits.

All participants were subjected to management according to the local COVID-19 protocol: MOH protocol version 1.4 November 2020. Full history of COVID-19 symptomatology and clinical examination was made.

Assessment of severity was carried out according to the Center of Disease Control (CDC) and United States National Institute of Health (2020). Cases with any sign or symptom of COVID-19 (such as fever, headache, cough, malaise, sore throat, muscular pain, nausea, vomiting, diarrhoea, loss of taste or smell) but no dyspnea, shortness of breath, or abnormal chest imaging were classified as mild illness. Moderate cases are people with lower respiratory illness, as determined clinically or radiologically, with an oxygen saturation (SpO2) of less than 94% on room air at sea level. In addition, those with a SpO2 of 94 percent on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) of 300 mm Hg, a respiratory rate of more than 30

breaths/min, or lung infiltrates of more than 50 percent have a severe illness. Finally, those with respiratory failure, septic shock, and/or multiple organ dysfunction are considered critical cases[10].

Clinical deterioration is defined as the deterioration of two points (from the status at randomization) on a Seven-category ordinal scale (WHO R&D Blueprint expert group). The seven-category ordinal scale consisted of the following categories: 1, not hospitalized with the resumption of normal activities; 2, not hospitalized, but unable to resume normal activities; 3, hospitalized, not requiring supplemental oxygen; 4, hospitalized, requiring supplemental oxygen; 5, hospitalized, requiring nasal high-flow oxygen therapy, noninvasive mechanical ventilation, or both; 6, hospitalized, requiring ECMO, invasive mechanical ventilation, or both; and 7, death. Thus, the clinical status scale ranged from 1 to 7[9]. To investigate the change in clinical status, we used the following equation: **Clinical status change = baseline clinical status – 14-day clinical status**. The minimum is – 6 and the maximum is + 6, with negative values mean deterioration and positive values mean improvement.

Full blood count with differential: the sample was 2 mL EDTA blood. Hemolyzer machine was used. Inflammatory markers: C Reactive Protein (CRP) (3 mL blood serum using ELISA Kit for CRP), ESR (2 mL citrate blood), Ferritin (3 mL blood serum using ELISA Kit for Ferritin), Lactate Dehydrogenase (LDH) (3 mL blood serum using ELISA Kit for LDH), D-dimer (2 mL citrate blood plasma using ELISA Kit for D-Dimer (D2D)). Arterial blood gases, whenever needed. Renal function tests: Urea and creatinine. Liver function tests: ALT, AST.

Assessments:

Baseline: Clinical status, inflammatory markers. At 14 days: Clinical status and inflammatory markers. Primary end-point: clinical deterioration two points increase on the seven-category scale. Secondary end-point: inflammatory markers.

Statistical methods:

The statistical analysis for efficacy and safety were made on the intent-to-treat population. All statistical tests were done using a significance level of 95%. A value for $P < 0.05$ was considered statistically significant. SPSS software (Statistical Package for the Social Sciences, version 25.0, SSPS Inc, Chicago, IL, USA) was used for the statistical analyses. Data was presented as (mean ± SD) for continuous variables, (median (IQR)) for ordinal and non-parametric data, and frequency & percentage for categorical variables. Comparisons wre made using Pearson Chi square or Phi test for categorical variable and the unpaired Student's t-test for continuous variables and other relevant tests.

RESULTS:

Baseline chracteristics:

Both the study group and the control group were comparable with regard to their baseline characteristics: as shown in Table 1. About 13.2% & 13.6% have DM, 27.1% 27.2% have hypertension of the colchicine group and the control group, respectively.

According to the CDC criteria, there was no statistically significant (p-value 0.553) difference between both groups as regards the severity of COVID-19, as shown in Table 1. The majority of cases, 92.5% & 88% of the colchicine group and the control group, respectively, were mild to moderate cases.

Table 1: Patients' demographics and baseline characteristics:

	Colchicine group		Control group		
	N = 129		N = 125		
	Number	%	Number	%	p-value
Gender					
Male	54	41.9%	55	44.0%	0.414
Female	75	58.1%	70	56.0%	
DM	17	13.2%	17	13.6%	0.921
Hypertension	28	21.7%	34	27.2%	0.308
Severity					
Mild	20	15.5%	22	17.6%	0.553
Moderate	98	76.0%	88	70.4%	
Severe	11	8.5%	15	12.0%	
	Mean	SD	Mean	SD	
Age, years	42.9	15.7	46.8	17.4	0.06
BMI, Kg/m^2	29.9	6.1	29.8	7.0	0.881

Symptoms and clinical status of COVID-19 patients at presentation:

Cough is the most frequent symptom in the colchicine group (75.2%) versus the control group (63.2%) (p-value 0.038). The most frequent symptom in the control group was fatigue/malaise (72.0%), while in the colchicine group, it was (70.5%). Other symptoms are shown in Figure 1.

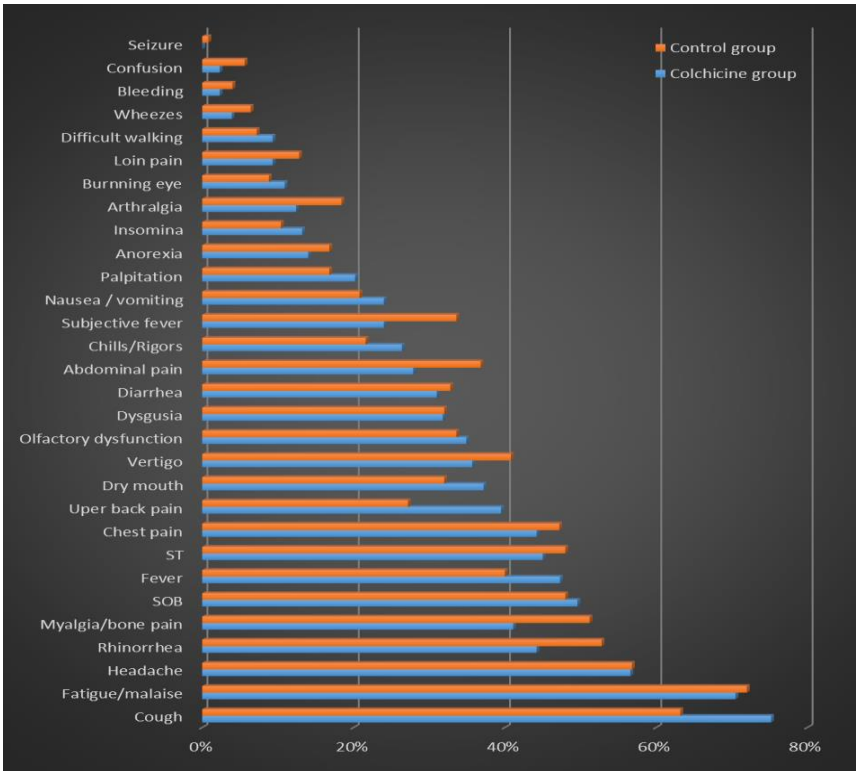

Figure 1: Reported symptoms at presentation

At presentation, there was no significant (p-value 0.957) difference between both groups regarding the clinical status according to the seven-category ordinal score. Around 81.4% of the colchicine group and 83.4% of the control group were not hospitalized with or without resumption of everyday activities, as shown in Table 2.

Table 2: Clinical status at presentation: Seven-category ordinal scale

	Colchicine		Control		
	N = 129		N = 125		
	N	%	N	%	p-value
1, not hospitalized with resumption of normal activities	19	14.7%	19	15.2%	0.957
2, not hospitalized, but unable to resume normal activities	86	66.7%	84	67.2%	
3, hospitalized, not requiring supplemental oxygen	20	15.5%	17	13.6%	
4, hospitalized, requiring supplemental oxygen	4	3.1%	5	4.0%	
5, hospitalized, requiring nasal high-flow oxygen therapy, noninvasive mechanical ventilation, or both	0	0.0%	0	0.0%	
6, hospitalized, requiring ECMO, invasive mechanical ventilation, or both	0	0.0%	0	0.0%	
7, death	0	0.0%	0	0.0%	

Neutropenia was seen in 41.9% & 31.2% of the colchicine and the control groups, respectively (p-value 0.078). Leucopenia was seen in 40.3% & 32.8% of the colchicine group and the control group, respectively (p-value 0.214). Lymphopenia was seen in 22.5% & 24.0% of the colchicine and the control groups, respectively (p-value 0.774). Other findings of the CBC are shown in Figure 2.

Labortory data and inflammatory markers at presentation:

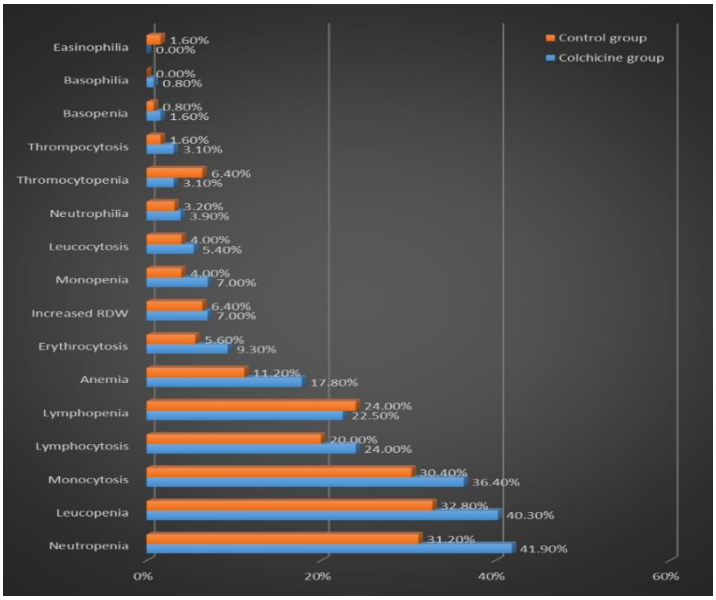

Figure 2: Finding in CBC at presentation

Both groups were comparable regarding the level of the following inflammatory markers at presentation: ferritin, CRP and ESR as shown in Table 3.

Table 3: Inflammatory markers at presentation

	Ferritin	CRP	ESR
	153	234	120
Colchicine group			
Mean	241.4	23.4	30.0
SD	273.7	30.0	24.8
Median	164.6	12.0	25.0
IQR	208.1	25.5	19.3
Control group			
Mean	225.6	26.0	28.2
SD	239.9	27.0	28.7
Median	153.9	18.0	18.3
IQR	1545.9	179.5	127.0
p-value	0.901	0.060	0.174

Clinical status at day 14:

On day 14, there was a significant (p-value 0.013) difference between groups regarding the clinical status according to the seven-category ordinal score. Around 89.9% of the colchicine group and 84.0% of the control group were not hospitalized with or without resumption of everyday activities, as shown in Figure 3.

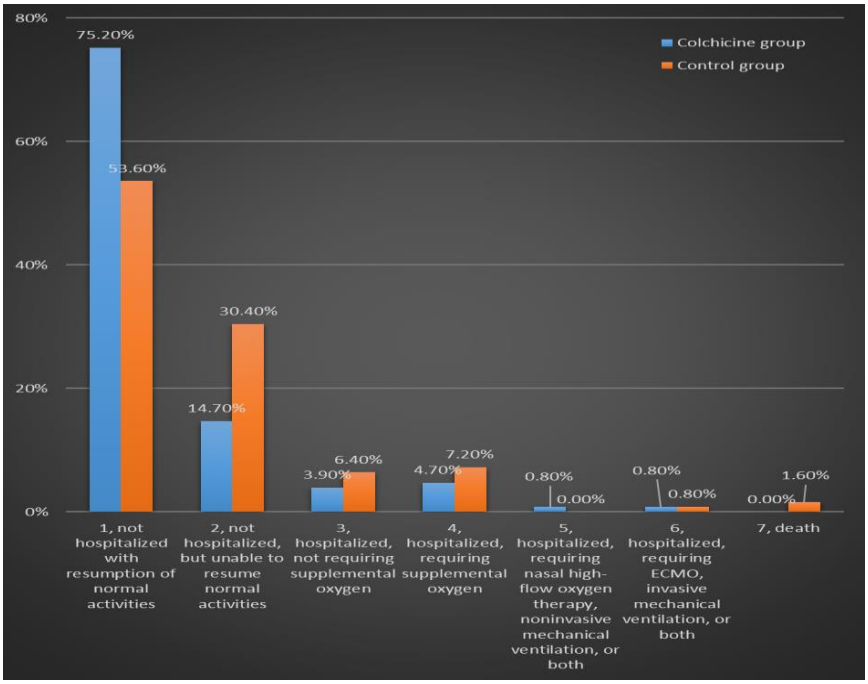

Figure 3: Clinical status at day 14

To investigate the change in clinical status, we used the following equation: Clinical status change = baseline clinical status – 14-day clinical status. The

minimum is –6 and the maximum is +6, with negative values mean deterioration and positive values mean improvement. The improvement in the clinical status in the colchicine group is significantly (p-value = 0.002) higher than in the control group. It was 0.64 (0.96) and 0.28 (0.99) in the colchicine and the control groups, respectively.

Inflammatory markers and other laboratory data at day 14:

On day 14, there was a significant (p-values < 0.001) difference between groups regarding the inflammatory markers CRP & ESR which were significantly lower in the colchicine group than in the control group. However, the ferritin was insignificantly (p-value = 0.078) lower in the colchicine group than in the control group, as shown in Table 6.

Table 4: Inflammatory markers at 14-day

	Ferritin	CRP	ESR
	153	234	120
Colchicine group			
Mean	184.3	10.6	13.3
SD	210.6	16.7	11.3
Median	111.4	4.0	10.1
IQR	189.8	10.8	12.0
Control group			
Mean	201.2	21.7	24.4
SD	202.5	23.8	24.9
Median	151.9	9.2	14.5
IQR	1381.7	97.1	113.6
p-value	0.079	< 0.001	< 0.001

DISCUSSION:

Because of the emergence of the pandemic of SARS-Cov2 infection and the Global burden of COVID-19 on the worldwide healthcare systems, it became mandatory for all researchers all over the globe to search for better preventive as well treatment strategies. The COVID-19 is primarily a pulmonary disease and has its hazardous effects on the lung in the form of ARDS, respiratory failure in the short term, and post-COVID-19 pulmonary fibrosis in the long term. Therefore, the intent behind this current study was to investigate the efficacy of an old treatment, colchicine 0.5 mg tablets, on the clinical outcomes and inflammatory markers.

In the current study, both the colchicine group and the control group are comparable regarding gender, age, BMI, and comorbid conditions (DM & hypertension). In addition, both groups are comparable regarding the severity of COVID-19. The majority of cases, 92.5% & 88% of the colchicine group and the control group, respectively, were mild to moderate cases. ***In agreement of this study***, one study **by Wu Z & McGoogan JM (2020)** in China showed that 81% were mild to moderate cases, and the rest, 19% were severe to critical[(11)] .

The most frequent symptoms encountered in our study were cough, fatigue/malaise followed by headache. Then, rhinorrhea, myalgia, SOB, fever, sore throat, and chest pain came next in their frequencies.

That is in accordance with another report in the USA that showed that 70% of COVID-19 cases experienced fever, cough, or SOB, 36% had myalgia, and 34% headaches[12]. Other reported symptoms in the study by ***Stokes et al., 2020*** are diarrhea, dizziness, rhinorrhea, anosmia, dysgeusia, sore throat, abdominal pain, anorexia, and vomiting[12]. These symptoms also were seen in our patients.

The clinical status in our study was reported according to the seven-category ordinal score. Arround 81.4% of the colchicine group and 83.4% of the control group have a score of 1 or 2 (not hospitalized). Neutropenia was seen in 41.9% & 31.2% of the colchicine and the control groups, respectively (p-value 0.078). Lecuopenia was seen in 40.3% & 32.8% of the colchicine and the control groups, respectively (p-value 0.214). Lympopenia was seen in 22.5% & 24.0% of the colchicine group and the control group, respectively (p-value 0.774).

The results of the current study showed a clinical benefit of colchicine. That was reflected on the clinical status at day 14 as there was a significant (p-value 0.013) difference between both groups regarding the clinical status according to the seven-category ordinal score with higher proportion (89.9%) of the colchicine group versus 84.0% of the control group were not hospitalized with or without resumption of everyday activities. The improvement in the clinical status in the colchicine group is significantly (p-value = 0.002) higher than in the control group. It was 0.64 (0.96) and 0.28 (0.99) in the colchicine and the control group, respectively. In addition, ***Deftereos et al. (2020)*** in their study, showed a significant clinical benefit from colchicine in patients with COVID-19. However, all of their cases were hospitalized COVID-19 cases[9].

There is limited anecdotal experience, and clinical trial data reported about colchicine to date in COVID-19. A retrospective review of the computerized healthcare database found no difference in baseline use of colchicine (0.53 vs. 0.48%) between patients with a positive RT-PCR result for SARS-CoV-2 (n = 1317) and those with a negative result (n = 13,203), suggesting a lack of protective effect for colchicine against SARS-Cov-2 infection; indication for and duration of colchicine use were unknown [13].

A case report of a patient with moderate COVID-19 treated with colchicine showed an improvement in symptoms and a reduction in levels of IL-6 [14].

Uncontrolled case series of 9 patients in a community setting with COVID-19 received colchicine (1 mg orally every 12 hours on day 1, then 1 mg daily until the third day of temperature <37.5°C); colchicine was initiated at a median of 8 days (range: 6-13 days) after symptom onset and after 3-5 days of spiking fever despite acetaminophen or antibiotic treatment. Defervescence occurred within 72 hours in all patients. One patient was hospitalized because of persistent dyspnea and discharged after 4 days of oxygen therapy. Basis for diagnosis of COVID-19 not stated. This study also postulated that treatment with colchicine early in the disease process might be more beneficial before the onset of ARDS[15].

We recommend adding colchicine to the current armamentorium of mangement of COVID-19.

Meticulous selection of cases to receive colchicine is necessary according to the different precausions of its usage. Drug-to-drug interactions should be considered first, as some of the medications used in COVID-19 interact with colchicine molecule. Finaly, risk-benefit evaluation should be made before including colchicine in the management of any case.

Conflicts of Interest: The authors state that the publishing of this paper is free of any conflicts of interest.

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تأثير الكولشيسين على على النتائج الأكلينيكية لمرض فيروس كورونا ٢٠١٩

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خلفية الدراسة: بسبب العبء العالمي لمرض فيروس كورونا ٢٠١٩ (COVID-19) وعواقب ما بعد ال COVID-19 على أنظمة الرعاية الصحية في جميع أنحاء العالم، من الضروري البحث عن استراتيجيات وقائية وكذلك علاجية أفضل.

هدف الدراسة: كان الهدف من هذه الدراسة الحالية هو التحقيق في آثار الكولشيسين على النتائج الاكلينيكية لمرضى ال COVID-19، ومستوى علامات الالتهاب أثناء المرض.

منهجية الدراسة: أجريت هذه الدراسة المقارنة العشوائية على المرضى الذين تم التأكد من إصابتهم بـ COVID-19 في مستشفى عزل عين شمس في الفترة من فبراير ٢٠٢١ ومايو ٢٠٢١. و قد وافق مجلس المراجعة المؤسسية و كذلك لجنة أخلاقيات البحث بجامعة عين شمس على الدراسة. تم اختيار ما مجموعه ٢٦٠ مشاركًا بشكل عشوائي مع تخصيص ١٣٠ لكل مجموعة على النحو التالي: مجموعة الدراسة (مجموعة الكولشيسين) (ن = ١٣٠): تضمنت المرضى الذين تلقوا بروتوكول علاج COVID-19 بالإضافة إلى الكولشيسين وفقًا لبروتوكول الدراسة. مجموعة التحكم (ن = ١٣٠): تضمنت المرضى الذين تلقوا بروتوكول علاج COVID-19 فقط بدون كولشيسين.

نتائج الدراسة: أظهرت نتائج هذه الدراسة أن كلا المجموعتين كانت قابلة للمقارنة من حيث العمر ومؤشر كتلة الجسم والجنس. شكلت الإناث ٥٨,١٪ و ٥٦,٠٪ من الحالات في مجموعة الكولشيسين ومجموعة التحكم على التوالي.

و عند رؤية الحالات لأول تقييم، فيما يتعلق بحدة المرض، كانت كلتا المجموعتين قابلة للمقارنة (القيمة الاحتمالية = ٠,٥٥٣). و في اليوم ١٤، كان التحسن في الحالة الاكلينيكية في مجموعة الكولشيسين ٠,٦٤ (٠,٩٦) أعلى بشكل ملحوظ (القيمة الاحتمالية = ٠,٠٠٢) مقارنة بالمجموعة الضابطة ٠,٢٨ (٠,٩٩).

خلاصة الدراسة: في الختام، إن التأثير المفيد للكولشيسين في حالات COVID-19 واضح بذاته لكل من الحالة الاكلينيكية وعلامات الالتهاب.