



# Dexamethasone in Treatment of Comorbid SARS-CoV-2 Patients Aged over 50 Years with Lung Injury over 50 %

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**Aim.** An efficacy assessment of steroid therapy in SARS-CoV-2 patients aged over 50 years with lung damage over 50 % (grade 3–4).

**Materials and methods.** A retrospective study of 158 SARS-CoV-2 patients hospitalised in April–June 2020 was conducted under the inclusion criteria: age over 50 years, chest computed tomography (CT) for COVID-19-associated pneumonia, C-reactive protein (CRP) >50 mg/L, anticoagulant therapy, no contraindications to steroids, no biologic therapy. Cohort 1 patients ( $n = 96$ ) received dexamethasone 4–12 mg/day, cohort 2 ( $n = 62$ ) — a standard non-dexamethasone therapy.

**Results.** Dexamethasone treatment associated with a significant alleviation of COVID-19-associated pneumonia in CT score ( $p = 0.001$ ), reduced fibrinogen ( $p = 0.001$ ), a trend to CRP reduction by day 8–10 and lower demand for oxygen therapy, including ventilatory support ( $p = 0.001$ ). Mortality rate was 19.8 and 75.8 % in cohorts 1 and 2, respectively ( $p = 0.001$ ).

**Conclusion.** Dexamethasone therapy 4–12 mg/day in SARS-CoV-2 patients aged 50+ years with grade 3–4 CT changes receiving LMWH from start of hospitalisation significantly improved CT scores and reduced mortality.

**Keywords:** COVID-19, dexamethasone, computed tomography, pneumonia

**Conflict of interest:** the authors declare no conflict of interest.

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## Дексаметазон в лечении коморбидных пациентов старше 50 лет, инфицированных SARS-CoV-2, с поражением легких более 50 %

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**Цель исследования:** оценить эффективность стероидной терапии у пациентов с SARS-CoV-2 в возрасте старше 50 лет с поражением легких более 50 % (3–4-й степени).

**Материалы и методы.** Проведено ретроспективное исследование 158 пациентов с подтвержденной инфекцией SARS-CoV-2, госпитализированных в апреле — июне 2020 г. Критерии включения: возраст старше 50 лет, компьютерная томография грудной клетки (КТ) при COVID-19-ассоциированной пневмонии, уровень С-реактивного белка (СРБ) более 50 мг/л, антикоагулянтная терапия, отсутствие противопоказаний к применению стероидов, отсутствие биологической терапии. Пациенты 1-й группы ( $n = 96$ ) получали дексаметазон 4–12 мг/сут. Группа 2 ( $n = 62$ ) получала стандартную терапию без дексаметазона.

**Результаты исследования.** Терапия дексаметазоном была связана со значительным улучшением показателей КТ пневмонии, ассоциированной с COVID-19 ( $p = 0,001$ ), снижением уровня фибриногена ( $p = 0,001$ ) и тенденцией к снижению СРБ к 8–10-му дню, снижению необходимости терапии кислородом, в том числе искусственной вентиляции легких ( $p = 0,001$ ). Смертность в 1-й группе составила 19,8 %, во 2-й — 75,8 % ( $p = 0,001$ ).

**Выводы.** Терапия дексаметазоном 4–12 мг/день у пациентов с подтвержденной инфекцией SARS-CoV-2 старше 50 лет с изменениями КТ 3–4-й степени, получающих НМГ с первых дней госпитализации, значительно улучшила показатели КТ и снизила уровень смертности.

**Ключевые слова:** COVID-19, дексаметазон, компьютерная томография, пневмония

**Конфликт интересов:** авторы заявляют об отсутствии конфликта интересов.

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## Introduction

A new coronavirus has been identified as SARS-CoV-2 can cause a potentially dangerous illness with a highly of lethal risk. Nowadays, experts have being considered a prognosis of the pathway and severity of the coronavirus infection course is determined not so much by the severity of viremia as by the peculiarities of the body's immune responses and associated organ damage, cytokine storm and thrombus formation [1–4]. There is also discussed a necessity for the immunosuppressive therapy in treating excessive cytokine response [3–5]. A corticosteroids usage for SARS-CoV-2 is debated during the current pandemic around the world. To date, a meta-analysis has been published by the World Health Organization (WHO), in which were presented data from seven RCTs of the corticosteroids use for a treatment of the patients with SARS-CoV-2 [6]. For the analysis were included 7184 patients totally, including 6425 patients from the RECOVERY study [7]. A data pooling suggests that systemic corticosteroids, reduce 28-day mortality in patients with critical (relative risk [RR] 0.80, 95 % CI 0.70–0.91) and severe (RR 0.80, 95 % CI 0.70–0.92) the course of the disease in compare to a conventional treatment or placebo. It also reduces a need for the invasive mechanical ventilation (RR 0.74, 95 % CI 0.59–0.93). In the case of mild SARS-CoV-2 infection, an administration of the systemic corticosteroids can increase the risk of death (RR 1.22, 95 % CI 0.93–1.61). A mortality reduces in the group of patients having taken corticosteroids was also confirmed by J. van Paassen's review, where he has combined 44 RCTs involving 20.197 patients and showed a significant decrease in mortality during treatment with corticosteroids (OR 0.72 (95 % CI 0.57–0.87) in compare with the patients without a steroid therapy. The results of these meta-analyzes have led to amendments into the treatment guidelines and actual recommendations for corticosteroids use in SARS-CoV-2. On September the 2-nd, 2020 WHO issued interim guidance to use dexamethasone and other corticosteroids for the treatment of SARS-CoV-2 [6].

In according to the document, an appointment of corticosteroids is justified for a treatment of the patients with severe and critical SARS-CoV-2 and it is not recommended in the case of a mild form of the disease. At the same time, there were published two other meta-analyzes, in which it

was not confirmed the influence of corticosteroids on the difference in mortality and the need for a mechanical ventilate in the patients with SARS-CoV-2 [8–10].

There are the different and sometimes opposite results in the published studies, so it is required the additional RCTs to determine the clinical characteristics of patients for whom it could be usefully the corticosteroid administration.

By applying the immunosuppressive therapy, a treatment of the patients with coronavirus infection requires the mandatory administration of low molecular weight heparin (LMWH), its influence is aimed to prevent the development of thrombotic complications and one has also had an anti-inflammatory effect [11, 12].

**The research aim** is to study an effectiveness of the corticosteroids use in a treatment of the comorbid SARS-CoV-2 patients 50+ years old, with lung damage of more than 50 % (3–4 degree).

## Materials and methods

A retrospective analysis of electronic medical records was carried out for 255 patients infected with SARS-CoV-2. The SARS-CoV-2 infection presence was confirmed with a polymerase chain reaction to define a positive result for the existed SARS-CoV-2 RNA. All of the patients signed an informed consent and having treated at the intensive care unit of the Sechenov University clinic in the period from 04/06/2020 to 06/05/2020. The study was approved by the clinical research Sechenov University ethics committee and was conducted in accordance with the Declaration of Helsinki.

The inclusion criteria of the studied patients were:

- age over 50 y.o.;
- the presence of changes in a computed tomography (CT) of the lungs (more than 50 % of the lungs (3–4 tbsp.) at the time of admission;
- one or more concomitant diseases presence;
- the repeated CT scan data from in 8–10 days from the admission date;
- the anticoagulant therapy (LMWH);
- C-reactive protein level was more than 50 mg/l.

The exclusion criterion was a dexamethasone taking within 6 months prior to hospitalization.

97 patients from the total number of patients were not met the inclusion criteria: age was less

than 60 ( $n = 19$ ), there were no changes on CT for the 3–4 stages at the time of admission ( $n = 9$ ), some of the patients were not received LMWH ( $n = 41$ ), there were no data of the repeated CT ( $n = 16$ ), the CRP level was less than 50 mg/l ( $n = 18$ ), the patients which had died during 11 days from the hospitalization moment ( $n = 35$ ). There were not prescribed a dexamethasone at the hospitalization beginning ( $n = 4$ ) and biological therapy ( $n = 3$ ).

The patients had taken no dexamethasone before the admission at the clinic. Thus, 158 patients were included at the final analysis. The patients were divided into the groups in according to the reception of dexamethasone: 96 patients having received dexamethasone, were included at the 1-st group, the 2-nd (control) group was consisted from 62 patients having not received dexamethasone. From the moment of hospitalization, all of the patients received the LMWH therapy (sodium enoxaparin) in a daily dose of 0.8–1.6 ml; the patients from the 1-st group have additionally taken dexamethasone at a dose of 4–12 mg/day for 8–10 days from the admission.

All of the observed patients received hydroxychloroquine and antibiotic therapy; nobody of the patients received any biological therapy.

The following patients' parameters were assessed at the admission: demographic data (gender, age); the presence of concomitant diseases — ischemic heart disease (IHD), arterial hypertension (AH), chronic obstructive pulmonary disease (COPD), diabetes mellitus (DM), malignant tumors; as well as the days quantity from the moment of fever onset before an admission at the hospital, body temperature, blood oxygen saturation  $\text{SpO}_2$  (%).

A dynamics of the data changes was analyzed for Lung CT data (percentage of lung lesion) and laboratory parameters: hemoglobin, platelets, leukocytes, neutrophils, lymphocytes, neutrophil-lymphocyte index (NLI), fibrinogen, C-reactive protein (CRP), international normalized ratio (INR).

To evaluate an efficacy of the treatment, the laboratory and instrumental data were analyzed and compared as at the patient's admission as the obtained data on the 8–10th day of treatment (the ending of dexamethasone intake in the 1-st group). There were also studied a hospital mortality and the need for a lung mechanical ventilation.

### Statistical data processing

The results of variables corresponding to the normal distribution are presented as a mean value with a standard deviation, in other cases — as the median (Me) and interquartile range (ICR,

values of 25–75 percentiles) or as a percentage. To test the statistical hypotheses we having used the Mann — Whitney  $U$ -test, Student's  $t$ -test, Fisher's exact test, and Pearson's chi-square test. The odds ratio (OR) and 95 % confidence interval (95 % CI) were also calculated. The  $p < 0.05$  value was taken as the criterion of significance. Statistical calculations were carried out with the Statistica 10 computer program.

### Data availability

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request

## Results

The patients from the both groups were matched for gender and age criteria. The other patients' criteria were evaluated at the admission moment: a body temperature, the hemoglobin concentration, the number of platelets, leukocytes, neutrophils, lymphocytes; the concentration of fibrinogen and CRP, the INR index and the lung damage percentage on CT were comparable into the both groups. The patients from the first group were hospitalized just in a few days from the date of a fever onset. In the patients from the second group, there were noticed a decrease in saturation ( $\text{SpO}_2$ ) and a tendency to the higher values of NLI (Table 1).

The groups were not differed in the concomitant diseases of the cardiovascular system presence, COPD, diabetes mellitus, and the presence of malignant neoplasms (Table 2). Antibiotics were prescribed to all of the patients, the frequency of the necessity to receive 3 or more kinds of antibiotics was not differed in the groups. A necessity for the oxygen therapy was more frequently in the second group ( $p = 0.007$ ). 44 (70.9 %) patients of the second group were transferred to the mechanical lung ventilation, while only 21 patients (21.8 %) (OR 3.4, 95 % CI 2.2–5.4,  $p = 0.001$ ) were transferred to the mechanical lung ventilation from the first group.

The main laboratory parameters dynamics during the treatment for both groups is presented in Table 3. By the 8–10th days of a hospitalization there was observed a statistically significant decrease in the volume of lung tissue lesions by CT ( $p = 0.001$ ), the level of fibrinogen ( $p = 0.001$ ) and an expressed tendency to the C-reactive protein decrease in the patients having received dexamethasone, which were not observed in the second group. There were observed an increase in neutrophils, NLI and platelets in all of the studied patients (Table 3).

*Table 1.* The main clinical criteria of the hospitalized patients from the studied groups at admission

| Key features                      | Group 1 (n = 96)   | Group 2 (n = 62)    | p            |
|-----------------------------------|--------------------|---------------------|--------------|
| Age, years                        | 61.7 ± 12.1        | 64.8 ± 13.7         | 0.22         |
| Male / Female                     | 53/43              | 36/26               | 0.72         |
| Disease period (days)             | 6.5 [4; 9]         | 4.5 [2; 7]          | <b>0.01</b>  |
| Body temperature, °C              | 37.6 [37.2; 38.1]  | 37.4 [36.8; 37.9]   | 0.14         |
| Saturation, SpO <sub>2</sub> , %  | 94 [90; 95]        | 92 [84; 95]         | <b>0.01</b>  |
| Lung involvement, CT %            | 60.0 [50; 75]      | 70.3 [50; 75]       | 0.07         |
| <b>Laboratory characteristics</b> |                    |                     |              |
| Hemoglobin, g/L                   | 121.5 ± 27.4       | 125.0 ± 22.2        | 0.63         |
| Platelets, ×10 <sup>9</sup> /L    | 204.5 ± 93.1       | 209.3 ± 112.5       | 0.72         |
| WBC, ×10 <sup>9</sup> /L          | 6.7 ± 4.3          | 7.1 ± 4.5           | 0.64         |
| Neutrophils, ×10 <sup>9</sup> /L  | 4.8 ± 3.0          | 5.3 ± 3.7           | 0.63         |
| Lymphocytes, ×10 <sup>9</sup> /L  | 1.2 ± 1.7          | 0.9 ± 0.4           | 0.31         |
| NLR                               | 3.7 [2.5; 6.6]     | 5.1 [2.9; 8.8]      | <b>0.057</b> |
| INR                               | 1.1 [1.1; 1.3]     | 1.2 [1.1; 1.3]      | 0.41         |
| Fibrinogen, g/L                   | 6.0 [4.6; 8.3]     | 6.4 [5.5; 8.1]      | 0.45         |
| CRP, g/L                          | 95.0 [47.7; 157.0] | 117.0 [76.0; 162.0] | 0.07         |

*Table 2.* The proportion of comorbidities and ongoing therapy in the studied patient groups

| Key features                          | Group 1 (n = 96) | Group 2 (n = 62) | p            |
|---------------------------------------|------------------|------------------|--------------|
| <b>Comorbid conditions</b>            |                  |                  |              |
| Obesity                               | 20 (20.8 %)      | 15 (24.2 %)      | 0.62         |
| Arterial hypertension                 | 61 (63.5 %)      | 46 (74.2 %)      | 0.16         |
| Diabetes mellitus                     | 27 (28.1 %)      | 23 (37.1 %)      | 0.23         |
| Chronic obstructive pulmonary disease | 5 (5.2 %)        | 5 (8.1 %)        | 0.47         |
| Ischemic heart disease                | 39 (40.6 %)      | 30 (48.4 %)      | 0.33         |
| Malignant tumors                      | 7 (7.3 %)        | 6 (9.7 %)        | 0.59         |
| <b>Therapy</b>                        |                  |                  |              |
| Antibiotic administration ≥ 3         | 94 (97.9 %)      | 60 (96.8 %)      | 0.94         |
| Oxygen therapy                        | 74 (77 %)        | 58 (93.5 %)      | <b>0.007</b> |

Table 3. The parameters dynamics in the studied groups by the 8–10th days of a treatment

| Comparable features                 | Baseline            | Day 8–10 день       | <i>p</i>     |
|-------------------------------------|---------------------|---------------------|--------------|
| <b>Group 1 (<i>n</i> = 96)</b>      |                     |                     |              |
| Lung involvement, CT %              | 60.0 [50; 75]       | 50.0 [50; 75]       | <b>0.001</b> |
| WBC, $\times 10^9/\text{L}$         | $6.7 \pm 4.3$       | $9.5 \pm 6.5$       | <b>0.001</b> |
| Neutrophils, $\times 10^9/\text{L}$ | $4.8 \pm 3.0$       | $7.5 \pm 5.1$       | <b>0.001</b> |
| Lymphocytes, $\times 10^9/\text{L}$ | $1.2 \pm 1.7$       | $1.5 \pm 2.5$       | 0.09         |
| NLR                                 | 3.7 [2.5; 6.6]      | 5.0 [3.0; 11.9]     | <b>0.002</b> |
| INR                                 | 1.1 [1.1; 1.3]      | 1.1 [1.0; 1.2]      | 0.64         |
| Fibrinogen, g/L                     | 6.0 [4.6; 8.3]      | 4.3 [3.1; 5.9]      | <b>0.001</b> |
| CRP, g/L                            | 95.0 [47.7; 157.0]  | 23.5 [4.0; 72.0]    | 0.09         |
| <b>Group 2 (<i>n</i> = 62)</b>      |                     |                     |              |
| Lung involvement, CT %              | 70.3 [50; 75]       | 70.0 [50; 75]       | 0.75         |
| WBC, $\times 10^9/\text{L}$         | $7.1 \pm 4.5$       | $9.3 \pm 4.9$       | <b>0.001</b> |
| Neutrophils, $\times 10^9/\text{L}$ | $5.3 \pm 3.7$       | $7.6 \pm 4.4$       | <b>0.000</b> |
| Lymphocytes, $\times 10^9/\text{L}$ | $0.9 \pm 0.4$       | $1.0 \pm 0.8$       | 0.48         |
| NLR                                 | 5.1 [2.9; 8.9]      | 8.4 [3.9; 16.2]     | <b>0.006</b> |
| INR                                 | 1.2 [1.1; 1.3]      | 1.3 [1.1; 1.4]      | 0.12         |
| Fibrinogen, g/L                     | 6.4 [5.5; 8.1]      | 6.9 [4.4; 8.3]      | 0.38         |
| CRP, g/L                            | 117.0 [76.0; 162.0] | 130.0 [67.5; 222.2] | 0.27         |

During the therapy with dexamethasone there was not observed any adverse events development in the patients.

A hospital mortality was 19.8 % in the 1-st group, one was 75.8 % ( $p = 0.001$ ) in the 2-nd group. The age of the deceased patients from the 1-st group was  $71.4 \pm 10.1$  years, one was  $66.8 \pm 12.4$  years in the 2-nd group (OR 4.3 (95 % CI 2.6–7.1)  $p = 0.001$ ) (Table 4).

## Discussion

The corticosteroids use for a treatment of the patients with coronavirus infection was remained a controversial and uncertain question for a long time yet. The SARS-CoV-2 pandemic has provided a powerful impulse for clinical research to clarify that controversy.

The recommendations to use the corticosteroids for SARS-CoV-2 are based on the data from

the RECOVERY study of 6425 patients in the UK. The authors have found that low-dose dexamethasone (6 mg for 10 days) was prescribed to 2104 patients and it significantly reduced mortality level for the patients were needed a respiratory support. The 35 % reduction of the patient's mortality was confirmed in patients on mechanical ventilation ( $p = 0.0003$ ) and it also decreased by 20 % in patients which were only needed an oxygen therapy ( $p = 0.0021$ ) in compare to the group of patients, which have being received no corticosteroids ( $n = 4321$ ). Nevertheless, there was noticed no significant effect of corticosteroids in the patients were required a respiratory intervention ( $p = 0.14$ ) [7].

Thus, it is obvious that the pathophysiological changes developing on the hyperinflammatory stage of SARS-CoV-2 infection allow glucocorticosteroids to demonstrate its immunomodulatory acting more convincingly.

Table 4. A mortality level compare for both groups

|                  | Group 1 (n = 96) | Group 2 (n = 62) | p            |
|------------------|------------------|------------------|--------------|
| Mortality, n (%) | 19 (19.8 %)      | 47 (75.8 %)      | <b>0.001</b> |
|                  | Age 71.4 ± 10.1  | Age 66.8 ± 12.4  | 0.001        |

Earlier, we presented the results of the positive corticosteroids influence for a treatment the patients with SARS-CoV-2 infection in our published study [13]. One of the analyzed criteria was the LMWH prescription of to all of the patients, it allowed to make a possible level of the differences more similar in therapy to demonstrate the effect of corticosteroids more clearly. To determine the effectiveness of dexamethasone in the treatment of comorbid SARS-CoV-2 patients over 50 years of age, with a severe course of the disease and lung damage of more than 50 % we having used this criterion in the present study too.

In this study, the average age of patients was over 60 years old, one is considered the most vulnerable age group (1) for which there is more often observing a critical course of the disease with an unfavorable (fatal) outcome for the patients in according to the WHO recommendations. We have shown the administration of dexamethasone promotes regression of inflammatory changes in the lungs ( $p = 0.001$ ) in comorbid patients with a large volume of pulmonary tissue damage and it's accompanied by positive dynamics of laboratory parameters (decrease in fibrinogen,  $p = 0.001$  and tendency to decrease in CRP), a decrease in the oxygen therapy necessity including artificial ventilation ( $p = 0.001$ ), as well as the better hospital survival of the SARS-CoV-2 patients ( $p = 0.001$ ). There was a good patient tolerance of the therapy. No any adverse events were identified with the use of moderate doses of dexamethasone.

A fact confirmation the corticosteroids have positive effected on the inflammation regression

and mortality reduction is in accordance with the pathophysiological rationale for this drug group and previous knowledge of their pleiotropic action [1-3]. Among the main effects of corticosteroids, it should be noted a prevention of the “cytokine storm” [2, 3, 13], reduction of excessive activation of the T-cell immune response [4], a prevention of adrenal insufficiency in the severe course of the disease [4]. It can allow the corticosteroids implement a whole range of the different effects to achieve the desired therapeutic effect.

The results of our study have contributed a new and very significant knowledge to the evidence base for the possible use of moderate doses of corticosteroids for the treatment of severe SARS-CoV-2 infection in comorbid patients over 50 years of age.

The limitation of the study is the lack of data on the virus clearance. In interpreting the data, it should be borne in mind the presented data apply only to the studied groups of patients who simultaneously received anticoagulants with or without dexamethasone.

## Conclusion

Being prescribed dexamethasone at a dose of 4–12 mg to the patients over 50 years old infected with SARS-CoV-2 with CT changes of 3–4 degree and receiving LMWH from the first days of a hospitalization. So, it contributes to achieve the positive dynamics of CT by the 8–10-th days and a level decrease of the hospital mortality.

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