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COVID-19 TREATMENT GUIDELINES FOR HOSPITALIZED PATIENTS AT ST. VINCENT'S MEDICAL CENTER, A LICENSED 473-BED COMMUNITY TEACHING HOSPITAL WITH A LEVEL II TRAUMA CENTER IN THE UNITED STATES

Valeriia Klymenko[1], Haritha Mopuru[1], Arsalan Alvi[1], Maria Morel[1], Nataliia Dyatlova[2], Michael Elias[1], David Regelmann[1]

[1]Quinnipiac University Frank H. Netter MD School of Medicine at St. Vincent's Medical Center, Bridgeport, Connecticut, USA;
[2]The Chicago Medical School Internal Medicine Residency Program at Northwestern McHenry Hospital, McHenry, Illinois, USA

Abstract. *The purpose* of the publication is to share our own experience and improve healthcare delivery for patients with COVID-19 infection in other countries. The article presents the indications for hospitalization, the basic principles of monitoring and treatment of COVID-19 hospitalized patients in a large US University Hospital (St. Vincent's Medical Center, Connecticut). The guideline is based on research data from RECOVERY, ACTT-1, SOLIDARITY, EMPACTA, REMAP-CAP, BLAZE-1, BLAZE-4 trials. The issues of antiviral, immunosuppressive, anti-inflammatory, anticoagulant monoclonal antibodies therapies are discussed.

Key words: COVID-19, guidance, treatment, USA.

Valeriia Klymenko,
MD — medical resident, PGY-2,
Tel: +15512578615,
email: Valeriia.Klymenko@hhchealth.org,
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Relevance. Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on January 12, 2020 [1]. SARS-CoV-2 spread rapidly and resulted in a global pandemic with more than 113 million infected people worldwide. The United States accounts for the highest number of cases and deaths, 28.5 million and 0.5 million respectively [2]. Overall, the mortality risk is 0.5–1.0 % (influenza 0.1 %), but the mortality increases significantly with comorbid disease states and age. According to the Center of Disease Control and Prevention (CDC) data, 8 out of 10 COVID-19 deaths reported in the United States have been in adults aged 65 years and older [3]. Hospitalized patients' mortality in New-York city hospitals at the beginning of the pandemic was 25-28 % and then decreased to 7-8 % by summer [4].

According to Johns Hopkins University and Medicine Coronavirus Resource Center, the severity of

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the disease varies. 80 % of infections are not severe, and patients recover without special treatment. Approximately 20 % of patients develop significant infection, 15 % require hospitalization and 5 % require Intensive Care Unit (ICU) admission [4]. Based on a cohort study, which was conducted among 8.516 veterans with COVID-19 in the US Department of Veterans Affairs Hospitals, the ICU mortality rate varied over time, with 22.9 % dying in March; 25.0 % dying in April and decreased to 12.8 % patients dying in August. A correlation was found between COVID-19 ICU mortality with COVID-19 ICU demand, and it showed that strains on critical care capacity were associated with increased mortality rates [5]. According to Wang et al. for COVID-19 acute respiratory distress syndrome (ARDS) in Wuhan, China, among patients admitted to a critical care setting, mortality ranged between 26 % and 61.5 %. In patients who received mechanical ventilation, mortality ranged between 65.7 % to 94 % [6].

Currently, neither fixed criteria for hospital admission nor a gold standard of patient management exists for this disease. This article seeks to share our experience and highlight the COVID-19 treatment guidelines at St. Vincent's Medical Center (SVMC), Connecticut (USA).

Results and discussion. The current criteria for the admission of patients to the hospital according to the National Institute of Health (NIH) COVID-19 Treatment Guidelines are any of the following:

- O_2 saturation of < 94 % on room air (RA);
- Respiratory rate (RR) of > 30 breaths/minute;
- PaO_2/FiO_2 < 300 mmHg;
- Lung infiltrates on the chest X-ray, computed tomography (CT) > 50 %;
- Altered mental status.

In addition to the NIH criteria, SVMC considers admission of patients aged 65 years and older who have moderate symptoms with interstitial pneumonia and multiple comorbidities, and who are clinically deemed to be at an increased risk for deterioration at home.

For all hospitalized patients diagnosed with COVID-19 or for patients under investigation, SVMC recommends placement in a negative pressure room, especially if patients require aerosol generating procedures and interventions such as nebulization, bilevel non-invasive positive pressure ventilation or high-flow oxygen supplementation. A baseline lab work for these patients includes a complete blood count (CBC) with differential, C-reactive protein (CRP), lactate dehydrogenase (LDH), ferritin, D-dimer, electrocardiography (ECG), troponin levels.

The differential diagnosis includes other respiratory viruses (influenza, respiratory syncytial virus), community enquired pneumonia (CAP), pulmonary embolism (PE), myocardial infarction (MI), acute chest syndrome (sickle cell disease), volume overload (congestive heart failure exacerbation, dialysis non-compliance).

Treatment. Some proposed therapies for this disease lack supporting data. The guidelines for treating patients with COVID-19 at St. Vincent's Medical Center are mostly based on the RECOVERY [7], ACTT-1 [8], SOLIDARITY [9], EMPACTA [10], REMAP-CAP [11], BLAZE-1, BLAZE-4 trial [12].

The pathogenesis of COVID-19 is mainly driven by two processes: viral SARS-CoV-2 replication at the beginning of the disease, and later, as the disease progresses, a development of an exaggerated immune/inflammatory response. Based on this understanding of COVID-19 pathogenesis, cornerstones of management consist of antiviral therapy in the early stages of the disease and transition to immunosuppressive/anti-inflammatory therapy after 7-10 days of the infection.

For antiviral COVID-19 therapy of hospitalized patients, remdesivir (RDV) has conferred clinical improvement [8]. The ACTT-1 trail showed that RDV administration shortened median recovery time for hospitalized patients with O_2 supplementation (but not mechanical ventilation) compared to placebo 10 days (95 % confidence interval (CI), 9 to 11) and 15 days (95 % CI, 13 to 18 days). However, RDV use has not shown any statistically significant mortality benefit. In the SOLIDARITY trial, which was conducted by the World Health Organization (WHO), RDV did not decrease a need for mechanical ventilation or mortality. Despite the lack of survival benefits, US hospitals continue to use RDV in the care of COVID-19 patients. The recommended dose of RDV is 200 mg IV on day 1, then 100 mg IV q 24h days 2-5. Exclusion criteria for RDV use are glomerular filtration rate < 30 mL/min using the Cockcroft-Gault formula, pregnancy/breast feeding, cirrhosis, alanine aminotransferase and aspartate aminotransferase > 5 times upper limit of normal.

Another treatment option for COVID-19 is antibody-based therapy. The Food Drug Administration (FDA) has issued emergency use authorization (EUA) for COVID-19 convalescent plasma. Although it is proposed as a useful treatment, there is no large randomized control trails (RCT) yet to show its benefit. One small RCT (160 patients) found that a severe respiratory disease developed in 13 out of 80 patients (16 %) who received convalescent plasma and in 25 out of 80 patients (31 %) who received placebo (relative risk, 0.52; 95 % CI, 0.29 to 0.94; P = 0.03), with a relative risk reduction of 48 %. On the other hand, on January 14th, 2021, the independent Data Monitoring Committee (DMC) reviewed the available safety and efficacy data of the convalescent plasma arm of the RECOVERY trial. The preliminary analysis based on 1.873 reported deaths among 10 .406 randomized patients shows no significant difference in the primary endpoint of 28-day mortality (18 % convalescent plasma vs. 18 % usual care alone; risk ratio 1.04, 95 % CI 0.95-1.14; P = 0.34).

Recently, November 21st, 2020, and February 9th, 2021, monoclonal antibodies specific to SARS-CoV-2 such as casirivimab/imdevimab and bamlanivimab received an EUA from the FDA [13]. In the US, monoclonal antibody therapy has been offered only to outpatients with mild to moderate COVID-19. In hospitalized patients, a monoclonal therapy has not shown any benefit to date and may even be associated with

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worse clinical outcomes [12]. Later stages of COVID-19 appear to be characterized by inflammation and coagulopathy instead of viral replication in earlier stages of the illness [14].

Bamlanivimab, casirivimab and imdevimab are neutralizing antibodies directed against the SARS-CoV-2 spike (S) protein which blocks viral entry. Based on the BLAZE-1 trial sponsored by a pharmaceutical company Eli Lilly, bamlanivimab in outpatients with mild and moderate COVID-19 showed a decrease in number of COVID-19 related hospitalizations or visits to the emergency room to 1.6 % compared to 6.3 % with placebo. Bamlanivimab is recommended for use in a single dose of 700 mg/kg IV infusion in one hour.

Weinreich et al. reported interim results of a trial with a combination of two monoclonal antibodies — casirivimab and imdevimab (REGN-COV2), which should be administered together. It also showed fewer hospitalizations/emergency room visits in REGN-COV2 group 3 % compared to 6 % in placebo-treated patients — (95 % CI, −16 % to 9 %). The dose is 1200 mg of casirivimab and 1200 mg of imdevimab [15].

Considering the results from RCT, the current guidelines at SVMC for inpatient monoclonal antibody use are the following:

Exclusion Criteria:

• Patients who were hospitalized due to COVID-19.

• Patients who require oxygen therapy due to COVID-19.

• Patients who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

Inclusion Criteria:

• Patient admitted for a non-COVID diagnosis, with weight at least 40 kg, and who has a documented positive result of a direct SARS-CoV-2 viral test within the last 10 days.

• All patients, who are 65 years old and older.

• Or if patients are younger than 65 years old but have comorbidities like — diabetes mellitus, Body mass index (BMI) > 35, chronic lung/heart conditions, chronic kidney disease Stage III or higher, Parkinson's disease, immunosuppressive condition, neurodevelopmental disorders.

• Patients who have medical-related technological dependence, for example tracheostomy, gastrostomy or positive pressure ventilation (not related to COVID-19).

For immunosuppressive/anti-inflammatory therapy which can have a beneficial effect in the late phase of COVID-19, corticosteroids (methylprednisolone, prednisone, dexamethasone) and IL-6 inhibitors (tocilizumab) are used at SVMC.

The RECOVERY trial provided evidence that dexamethasone administered 6 mg once a day reduced a 28-day mortality among patients receiving invasive mechanical ventilation (29.3 % vs. 41.4 %; rate ratio, 0.64; 95 % CI, 0.51 to 0.81) and those receiving oxygen without mechanical ventilation (23.3 % vs. 26.2 %; rate ratio, 0.82; 95 % CI, 0.72 to 0.94), but not among those without respiratory support (17.8 % vs. 14.0 %; rate ratio, 1.19; 95 % CI, 0.92 to 1.55).

Tocilizumab is an FDA-approved anti-IL6R agent for Chimeric antigen receptor (CAR) — T-cell cytokine release syndrome and rheumatoid arthritis. Tocilizumab should be given 8 mg/kg once, if CRP continues to rise and there are increased O_2 requirements within 24-48 hours of steroid therapy. Laboratory tests necessary prior to tocilizumab administration include interferon-gamma release assay, viral serology including human immunodeficiency virus (HIV) and hepatitis C and B antibodies. The EMPACTA demonstrated that, in the tocilizumab group, the cumulative percentage of patients who had received mechanical ventilation or who had died by day 28 was 12.0 % (95 % CI, 8.5 % to 16.9 %) and 19.3 % (95 % CI, 13.3 % to 27.4 %) in the placebo group (hazard ratio for mechanical ventilation or death, 0.56; 95 % CI, 0.33 to 0.97; P = 0.04). This trial did not, however, demonstrate improvement with tocilizumab in the overall survival rate. Death from any cause by day 28 occurred in 10.4 % of the patients in the tocilizumab group and 8.6 % of those in the placebo group (95 % CI, 5.2 % to 7.8 %), which was not statistically significant. On the other hand, on February 11th, 2021, the RECOVERY tocilizumab arm demonstrated that tocilizumab reduces the risk of death among hospitalized patients with severe COVID-19, a need for mechanical ventilation, as well as length of hospital stay. For instance, 29 % of the patients died in the tocilizumab group within 28 days compared to 33 % patients in the usual care group (rate ratio 0.86 %; 95 CI 0.77 to 0.96; p = 0.007), which constitutes an absolute difference of 4 % and number needed to treat was 25 patients. Among patients not on invasive mechanical ventilation, tocilizumab significantly reduced a chance of progressing to invasive mechanical ventilation or death from 38 % to 33 % (risk ratio 0·85, 95 % CI 0.78 to 0.93, P = 0.0005). In addition, the REMAP-CAP interleukin-6 receptor antagonist trail showed that use of tocilizumab should be avoided in patients with any of the following: significant immunosuppression, especially in the settings of other biologic immunomodulating drugs use, alanine transaminase >5 times the upper limit of normal, high risk for gastrointestinal perforation, an uncontrolled, serious bacterial, fungal, or non-SARS-CoV-2 viral infection; absolute neutrophil count < 500 cells/ml, platelet count < 50.000 cells/ml [16].

In addition to medical management, COVID-19 patients with ARDS and a ratio of the partial pressure of arterial oxygen (PaO_2) to the fraction of inspired oxygen (FiO_2) (P/F ratio) of less than 150 mm Hg could benefit from early prone-positioning. According to PROSERVA, a multicenter, prospective, randomized, controlled trial, with 466 assigned ARDS patients, early application of prolonged (16 hours) prone-positioning sessions significantly decreased mortality. The 28-day mortality was 16.0 % in the prone group and 32.8 % in the supine group (P < 0.001) and 90-day mortality was 23.6 % and 41.0 % respectively (P < 0.001). Of course, in all inter-

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ventions it is necessary to consider possible risks, which include endotracheal tube displacement and loss of airway [17].

Anticoagulation in COVID-19 patients remains a controversial topic. A retrospective study in two French intensive care units where lower extremities Doppler ultrasound was mandated for the COVID-19 patients, showed that the overall rate of venous thromboembolism (VTE) VTE was 69 % [18]. Another retrospective study conducted in Wuhan; China reported a 5 % of stroke incidence amongst hospitalized patients with COVID-19 [19]. Moreover, a retrospective review of 183 patients with COVID-19 found that 71.4 % of non-survivors and 0.6 % of survivors showed evidence of disseminated intravascular coagulation (DIC) [20]. Despite the rising number of reports with an increased risk of VTE in COVID-19 patients, there are currently not enough well-designed randomized trials to estimate the incidence of thrombotic complications among COVID-19 patients and determine risks, benefits, and an adequate dosage of anticoagulation therapy. On June 2nd, 2020, CHEST Guideline and Expert Panel Report was published on the prevention, diagnosis, and treatment of VTE in patients with COVID-19 [21]. This article is a systematic review and critical analysis of the literature based on 13 population, intervention, comparator, outcome questions resulted in 22 statements.

Summary of CHEST guideline and the expert panel report:

- Anticoagulant thromboprophylaxis is recommended in critically ill and suggested in acutely ill COVID-19 patients.
- The most preferable inpatient anticoagulant is low molecular weight heparin (LMWH) over fondaparinux, unfractionated heparin (UFH) and direct oral anticoagulant (DOAC). UFH might be preferred in patients with high bleeding risk or sever renal impairment.
- DOAC is not recommended for using in acutely and critical ill patients due to a high risk of rapid clinical deterioration, high likelihood of drug-drug interactions and acute kidney injury.
- Use standard dose anticoagulant for VTE prophylaxis over intermediate or full treatment dose, as there is a lack of RCT to justify higher intensity anticoagulant thromboprophylaxis in COVID-19.
- Inpatient thromboprophylaxis is only recommended and not following the discharge.
- Antiplatelet agents are not recommended for VTE prevention in critically ill COVID-19 patients.
- Mechanical thromboprophylaxis was suggested in acutely and critically ill patients with active bleeding or in increased risk of bleeding.

Conclusion. Familiarity with COVID-19 guidelines for hospitalized patients at SVMC in the USA can help doctors improve medical care in other countries.

КЕРІВНИЦТВО З ЛІКУВАННЯ COVID-19 ДЛЯ ГОСПІТАЛІЗОВАНИХ ПАЦІЄНТІВ В ЛІЦЕНЗОВАНОМУ 473-ЛІЖКОВОМУ НАВЧАЛЬНОМУ МЕДИЧНОМУ ЦЕНТРІ СВ. ВІНСЕНТА З ТРАВМАТОЛОГІЧНИМ ЦЕНТРОМ II РІВНЯ В СПОЛУЧЕНИХ ШТАТАХ АМЕРИКИ

В. Клименко[1], Х. Мупуру[1], А. Алві[1], М. Морель[1], Н. Дятлова[2], М. Еліас[1], Д. Регелманн[1]
[1]Медичний центр Святого Вінсента, Медична допомога Гартворда, Бріджпорт, СТ (США);
[2]Програма Резидентури Внутрішньої Медицини Чиказької Медичної Школи в Північно-Західній Лікарні Мак-Генрі, Мак-Генрі, Іллінойс, США

Резюме. *Мета публікації* — обговорення власного досвіду для підвищення ефективності медичної допомоги пацієнтам з коронавірусною інфекцією. У статті представлено покази для госпіталізації, основні принципи спостереження і терапії хворих з інфекцією COVID-19 у великій університетській клініці США (St. Vincent's Medical Center, штат Коннектикут). В основу гайдлайну покладені дані досліджень RECOVERY, ACTT-1, SOLIDARITY, EMPACTA, REMAP-CAP, BLAZE-1, BLAZE-4. Розглянуто питання противірусної, імуносупресивної, протизапальної, антикоагулятної терапії, застосування моноклональних антитіл.
Ключові слова: COVID-19, керівництво, лікування, США.

Valeriia Klymenko,
MD — medical resident, PGY-2,
Tel: +15512578615,
email: Valeriia.Klymenko@hhchealth.org,
Астма та Алергія, 2021, № 3, С. 50–55.

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РУКОВОДСТВО ПО ЛЕЧЕНИЮ COVID-19 ДЛЯ ГОСПИТАЛИЗИРОВАННЫХ ПАЦИЕНТОВ В ЛИЦЕНЗИРОВАННОМ 473-КОЕЧНОМ УЧЕБНОМ МЕДИЦИНСКОМ ЦЕНТРЕ СВ. ВИНСЕНТА С ТРАВМАТОЛОГИЧЕСКИМ ЦЕНТРОМ II УРОВНЯ В СОЕДИНЕННЫХ ШТАТАХ АМЕРИКИ

В. Клименко[1], Х. Мупуру[1], А. Алви[1], М. Морель[1], Н. Дятлова[2], М. Элиас[1], Д. Регелманн[1]

[1]Медицинский центр Святого Винсента, Медицинская помощь Гартворда, Бриджпорт, CT, США;

[2]Программа Резидентуры Внутренней Медицины Чикагской Медицинской Школы в Северо-Западной Больнице Мак-Генри, Мак-Генри, Иллинойс, США

Резюме. *Цель публикации* — обсуждение собственного опыта для повышения эффективности медицинской помощи пациентам с коронавирусной инфекцией. В статье представлены показания для госпитализации, основные принципы наблюдения и терапии больных с инфекцией COVID-19 в крупной университетской клинике США (St. Vincent's Medical Center, штат Коннектикут). В основу COVID-19 положены данные исследований RECOVERY, ACTT-1, SOLIDARITY, EMPACTA, REMAP-CAP, BLAZE-1, BLAZE-4. Рассмотрены вопросы противовирусной, иммуносупрессивной, противовоспалительной, антикоагулятной терапии, применения моноклональных антител.

Ключевые слова: COVID-19, руководство, лечение, США.

Valeriia Klymenko,
MD — medical resident, PGY-2,
Tel: +15512578615,
email: Valeriia.Klymenko@hhchealth.org,
Астма и Аллергия, 2021, № 3, С. 50–55.

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Valeriia Klymenko
MD, PGY-2
Quinnipiac University Frank H. Netter MD School of Medicine at St. Vincent's Medical Center, Bridgeport, Connecticut, USA
ORCID ID
https://orcid.org/0000-0002-7264-2593

Haritha Mopuru
MD, PGY-2
Quinnipiac University Frank H. Netter MD School of Medicine at St. Vincent's Medical Center, Bridgeport, Connecticut, USA
ORCID ID
https://orcid.org/0000-0001-6523-9846

Arsalan Alvi
MD, PGY-3
Quinnipiac University Frank H. Netter MD School of Medicine at St. Vincent's Medical Center, Bridgeport, Connecticut, USA
ORCID ID
https://orcid.org/0000-0003-4233-938X

Maria More
MD, PGY-1
Quinnipiac University Frank H. Netter MD School of Medicine at St. Vincent's Medical Center, Bridgeport, Connecticut, USA
ORCID ID
https://orcid.org/0000-0002-8984-1636

Michael Elias
MD, Critical care attending
Quinnipiac University Frank H. Netter MD School of Medicine at St. Vincent's Medical Center, Bridgeport, Connecticut, USA
ORCID ID
https://orcid.org/0000-0002-8271-1329

David Regelmann
MD, Program Director, Clinical Educator, Hospital Medicine
Quinnipiac University Frank H. Netter MD School of Medicine at St. Vincent's Medical Center, Bridgeport, Connecticut, USA
ORCID ID
https://orcid.org/0000-0002-1291-8172

Nataliia Dyatlova
MD, PGY-2
The Chicago Medical School Internal Medicine Residency Program at Northwestern McHenry Hospital, McHenry, Illinois, USA
ORCID ID
https://orcid.org/0000-0001-6267-2038

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