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EFFICACY OF MOLNUPIRAVIR IN COVID-19 INFECTION TREATMENT

EFIKASNOST MOLNUPIRAVIRA U LEČENJU COVID-19 INFEKCIJE

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Abstract
Introduction. Molnupiravir is an orally administered antiviral agent approved for the treatment patients with mild to moderate coronavirus disease 2019 caused by severe acute respiratory syndrome coronavirus 2. Its antiviral effect is based on the inhibition of viral replication. The aim of this study was to evaluate the effectiveness and safety of molnupiravir in clinical practice. **Material and Methods**. This retrospective study included 74 non-hospitalized patients with mild to moderate clinical presentation who were treated with molnupiravir at the Covid Hospital of the University Clinical Center of Vojvodina during 2022. Treatment efficacy was assessed based on the occurrence of hospitalization or death within 28 days after therapy initiation. **Results**. Disease progression requiring hospitalization occurred in 4 of 74 patients (5.4%). No deaths were recorded during the 28–day follow-up. Molnupiravir treatment was not associated with a significant reduction in viral load by day 5 of therapy. **Conclusion**. When administered within the first three days after symptom onset, molnupiravir appears to reduce the risk of hospitalization and mortality.
Keywords: Antiviral Agents; COVID-19; SARS-CoV-2; Hospitalization; Mortality; Treatment Outcome

Sažetak
Uvod. Molnupiravir je oralni antivirusni lek koji je odobren za lečenje pacijenata sa lakom i srednjeteškom kliničkom slikom *Severe acute respiratory syndrome coronavirus-2* infekcije. Patofiziološki smanjuje replikaciju virusa. Cilj istraživanja bio je proceniti efikasnost i sigurnost primene molnupiravira. **Materijal i metode**. Retrospektivna analiza koja obuhvata 74 nehospitalizovana pacijenta lečena u Kovid bolnici Univerzitetskog kliničkog centra Vojvodine tokom 2022. godine sa lakom ili srednjeteškom kliničkom slikom. Efikasnost je ispitivana na osnovu broja hospitalizacija ili smrtnog ishoda u toku 28 dana. **Rezultati.** Istraživanje je pokazalo da je samo kod 4/74 (5,4%) došlo do razvoja težeg oblika bolesti i potrebe za hospitalnim lečenjem. Preživljavanje je bilo do 28 dana kod svih pacijenata. Lečenje molnupiravirom nije bilo povezano sa smanjenjem broja virusnih čestica petog dana terapije. **Zaključak.** Ako se primeni u prva tri dana od pojave simptoma molnupiravir smanjuje broj hospitalizacija i smrtnih ishoda.
Ključne reči: antivirusni lekovi; COVID-19; SARS-CoV-2; hospitalizacija; mortalitet; ishod lečenja

Introduction

The coronavirus disease 2019 (COVID-19) pandemic has resulted in approximately 775 million confirmed cases and more than 7 million documented deaths worldwide as of April 2025, according to date published by the World Health Organization (WHO) [1]. In the Republic of Serbia, approximately 2.6 million individuals have been infected, with 18,307 reported deaths [2]. A substantial proportion of patients infected with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) required hospitalization, particularly older adults over 65 years of age and those with underlying comorbidities [3]. Given the potential of SARS-CoV-2 to cause severe acute respiratory syndrome and fatal outcomes, the development of effective therapeutic strategies aimed at reducing disease progression, hospitalization, and mortality has been major clinical priority [4].

Molnupiravir is a direct-acting oral antiviral agent that has demonstrated efficacy in reducing SARS-CoV-2 replication and viral RNA levels in the nasopharynx [5,6]. It is generally well tolerated, with a favorable safety profile; however, it is not indicated for use in children or pregnant women [4]. Molnupiravir is a nucleoside analogue that inhibits viral replication of several RNA viruses, including SARS-CoV-2. It inhibits the viral enzymes RNA polymerase and reverses protease. After intracellular conversion to its active triphosphate form, molnupiravir is incorporated into viral RNA in place of cytidine, leading to the accumulation of mutations that ultimately prevent effective viral replication [7,8]. Clinical trials and real-world studies have demonstrated that molnupiravir reduces the risk of severe outcomes in patients with mild to moderate COVID-19 who are at increased risk of disease progression [9]. The drug is administered

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Abbreviations

SARS-CoV-2 – severe acute respiratory syndrome coronavirus-2
COVID 19 – Corona virus disease
WHO – World Health Organization
MVL – mean viral load
RNA – ribonucleic acid
FDA – Food and Drug Administration
UCCV – University Clinical Center of Vojvodina
GCP – good clinical practice
RT-PCR – reverse transcription polymerase chain reaction
CRP – C-reactive protein
AST – aspartate aminotransferase
ALT – alanine transaminase
GGT – gamma-glutamyltransferase

orally at a dose of 800 mg every 12 hours for five days [10]. According to studies by Mahase and Gentile, molnupiravir administration reduced the risk of hospitalization or death by approximately 50% among non-hospitalized adults with mild to moderate COVID-19 who were at high risk for severe disease [8,10]. By the end of 2021, the research was carried out on 10 million of patients [10]. In the Republic of Serbia, molnupiravir was introduced into clinical practice in early 2022, followed by the approval of another oral antiviral agent, nirmatrelvir/ritonavir, for emergency use by the U.S. Food and Drug Administration (FDA).

The aim of this study was to evaluate the effectiveness and safety of molnupiravir administration.

Material and Methods

The study was designed as a retrospective observational study involving 74 non-hospitalized patients who were examined and treated on an outpatient basis at the COVID Hospital of the University Clinical Center of Vojvodina (UCCV). Patient enrollment began in early 2022, coinciding with the introduction of molnupiravir into clinical use in Serbia.

The study was approved by the Ethics Committee of UCCV and conducted in accordance with Good Clinical Practice (GCP) guidelines. Data were collected through a review of standard medical documentation and the internal UCCV clinical database.

The inclusion comprised adult patients of both sexes with confirmed SARS-CoV-2 infection, diagnosed by either a rapid antigen test or reverse transcription polymerase chain reaction (RT-PCR) performed in reference laboratories. Patients were required to present within five days of symptom onset and to have a mild to moderate clinical form of COVID-19, as defined by the WHO Clinical Progression Scale **(Table 1)** [11].

Exclusion criteria included age under 18 years, current hospitalization at the time of diagnosis, failure to meet diagnostic criteria for COVID-19, chronic dialysis, pregnancy or breastfeeding, severe neutropenia (absolute neutrophil count < 0.5×10^9/L), and thrombocytopenia (platelet count <100×10^9/L).

All patients received molnupiravir at the dose of 800 mg twice per day, in accordance with the national treatment protocol [12].

The following data were recorded for each patient: demographic characteristics, clinical presentation, vital signs, comorbidities, treatment duration, and clinical outcomes. At baseline, all patients underwent routine laboratory testing, including complete blood count with differential, creatinine and urea, electrolytes (sodium, potassium, chloride), bilirubin, C-reactive protein (CRP), D-dimer, and liver function tests (aspartate aminotransferase [AST], alanine transaminase [ALT], and gamma-glutamyltransferase [GGT]). Chest radiography was performed in all patients as part of standard diagnostic evaluation. Pneumonia was diagnosed based on a combination of clinical findings, laboratory results, and radiological evidence.

The effectiveness of molnupiravir was evaluated based on its ability to reduce disease progression, hospitalization, and mortality. Patients were followed for 28 days after treatment initiation. The primary outcome was the incidence of hospitalization for any

Table 1. World Health Organization Clinical Progression Scale

Patient state	Descriptor	Score
Uninfected	Uninfected: no viral RNA detected	0
Ambulatory mild disease	Asymptomatic: viral RNA detected	1
	Symptomatic: Independent	2
	Symptomatic: Assistence needed	3
Hospitalised: moderate disease	Hospitalised: No oxygen therapy	4
	Hospitalised: Oxygen by mask or nasal prongs	5
Hospitalised: severe diseases	Hospitalised: Oxygen by NIV or high flow	6
	Intubation and mechanical ventilation p02/Fi02 >150 or Sp02/Fi02 >200	7
	Mechanical ventilation Sp02/Fi02 < 150 (Sp02/Fi02 <200) or vasopressors	8
	Mechanical ventilation Sp02/Fi02 < 150 and vasopressors, dialysis or ECMO	9
Dead	Dead	10

cause or death within 28 days in patients who received at least one dose of molnupiravir and were not hospitalized prior to treatment initiation.

Adverse events were evaluated during the entire treatment period and 14 days after the end of treatment; data on serious adverse events associated with the applied treatment regimen were collected until the end participation in the, up to day 28.

Antiviral activity was assessed by evaluating viral clearance, defined as RT-PCR negativity of nasopharyngeal swabs on day 5 of treatment.

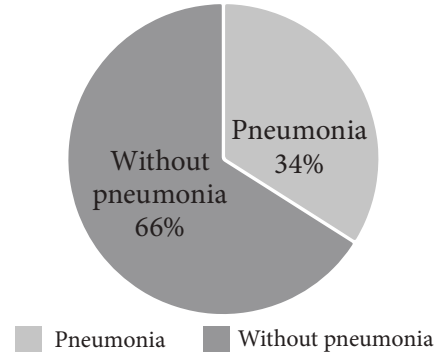
Statistical analysis was performed using IBM SPSS Statistics software, version 20.0.

Categorical variables were analyzed using the χ^2 test or Fisher's exact test, as appropriate. Continuous variables were expressed as mean ± standard deviation for normally distributed data or as median with interquartile range for non-normality distributed data. Given that most variables deviated from normal distribution, nonparametric tests were applied where appropriate. A p-value of <0.05 was considered statistically significant. Results are presented in tables and graphs with accompanying textual interpretation.

Results

The study population consisted of 74 non-hospitalized patients treated on an outpatient basis at the COVID Hospital of the UCCV who met the inclusion criteria. The mean age was 63.82 ± 23.7 years (range: 23-96). The cohort included an equal number of male and female patients (37/74, (50%) each).

Among patients with confirmed SARS-CoV-2 infection, 62 (83.73%) were vaccinated, while 12 (16.21%) were unvaccinated. The Sinopharm/BBIBP vaccine was the most frequently administered, accounting for 40/62 (67.74%) of vaccinated patients, followed by Pfizer/BioNTech in 16/62 (25.80%), and other vaccines in 6/62, (9.67%). The predominance of the Sinopharm/BBIBP vaccine was statistically significant compared with Pfizer/BioNTech and other vaccines



Graph 1. Presence of pneumonia at admission

(χ^2 = 10.28; p = 0.001). Comorbidities were common, with 55/74 patients (74.32%) having at least one comorbidity. Cardiovascular diseases and risk factors were the most prevalent, present in 47/55 patients (85.45%), followed by diabetes mellitus in 17/55 (30.95%) and obesity in 17/55 (30.95%).

Molnupiravir therapy was initiated within three days of symptom onset in the majority of patients; only four patients received treatment on the fourth day after symptom onset, in accordance with national treatment guidelines.

At baseline, radiologically confirmed pneumonia was present in 25/74 patients (34%) (**Graph 1).**After five days of treatment with molnupiravir, radiological regression of pneumonia was observed in 8/25 patient (32%), although this finding did not reach statistical significance (χ^2 =3.24; p = 0.07). Four patients experienced disease progression with worsening pneumonia and required hospitalization.

According to the WHO Clinical Progression Scale, 49/74 patients (66%) presented with a mild ambulatory form of disease (score 2), while 25/74 (34%) had a moderate ambulatory form (score 3) at baseline. Disease progressed requiring hospitalization occurred in 4/74 patients (9.45%). Among these, three required oxygen supplementation via face mask (score 5), and one patient required invasive mechanical ventilation (score 7). Survival through day 28 was achieved in all

Table 2. Adverse event incidence

Adverse event	Molnupiravir (N=74)
Patients with adverse events	Number (percentage)
Adverse event	22/74 (29.77%)
Adverse event related to drug administration	0
Serious adverse event	0
Fatal outcome	0
Nausea	15/22 (68.18%).
Emesis	3/22 (13.63%)
Diarrhea	3/22 (13.63%)
Headache	1/22 (4.54%)

Table 3. Biochemical parameters of patients

Biochemical parameter	Initial values (N = 74)	Third day treatment values (N = 74)
Leukocytes (4.00 - 10.00 x 10^9/L)	6.36 (3.34 – 13.55)	6.14 (3.36-10.06)
Lymphocytes (20 - 40%)	25.12 (10-46)	29.8 (11-53.2)
Neutrophils (50 - 75%)	64 (39-88)	62.185 (32.8-80)
Erythrocytes (4.2 - 6.00 x 10^{12}/L)	4.73 (3.7-6.0)	4.71 (3.78- 5.97)
Hemoglobin (130-170 g/L)	144 (114-171)	147 (115-170)
Hematocrit (0.400- 0.540 L/L)	0.452 (0.304 – 0.554)	0.514 (0.33-0.459)
Thrombocytes (140 – 400 x 10^9/L)	186 (82- 286)	202 (90-390)
CRP (< 5.0 mg/L)	20.40 (1-114)	12.1 (1-193)
Urea (2.5 - 7.5 mmol/L)	5.99 (2.4-11.4)	6.18 (2.7-15.7)
Creatinine (64 - 111 mmol/L)	83.08 (54-139)	83.23 (59-117)
Na (136 – 145 mmol/L)	140.12 (134-145)	140.49 (135-147)
K (3.5 – 5.5 mmol/L)	4.01 (3.3-5.2)	4.10 (3.5-5.6)
Cl (98– 107 mmol/L)	102.29 (94-109)	102.82 (95-109)
AST (5-34 U/L)	29.97 (12-67)	30.43 (15-59)
ALT (5-55 U/L)	34.67 (9-83)	34.32 (11-80)
GGT (11-59 U/L)	37.39 (8-98)	37.36 (8-86)
D dimer (< 0.5 mg/L FEU)	0.59 (0.22-2.45)	0.56 (0.2-3.06)
Procalcitonin (0.00 - 0.05 ng/mL)	0.05 (0.05)	0.556 (0.05-5.64)

CRP – C-reactive protein, Na - Sodium, K – Potassium, Cl – Chloride, AST – Aspartate aminotransferase, ALT – Alanine transaminase, GGT – Gamma-glutamyltransferase

patients, including those who discontinued outpatient follow-up and those who required hospitalization.

Adverse events were reported in 22/74 patients (29.77%). The most frequently observed adverse event was nausea, reported by 15/22 patients (68.18%). No serious adverse events related to molnupiravir treatment were recorded **(Table 2).**

Laboratory parameters measured at baseline and on day 3 of treatment are presented in **Table 3**. Overall, biochemical and hematological values remained without reference ranges, with no clinically relevant or statistically significant changes observed during treatment.

Clinical improvement, defined as symptom resolution or marked symptom reduction, was observed in the majority of patients. Complete symptom resolution by day 5 occurred in 49/74 patients. In the remaining non-hospitalized patients, gradual clinical improvement was documented between days 5 and 10. No deaths were recorded during the 28-day follow-up period.

At baseline, RT-PCR testing for SARS-CoV-2 was performed in 22/74 (29.77%) patients, while the remaining patients were diagnosed using rapid antigen test. Follow-up RT-PCR testing on day 5 was available for 42/74 patients (56.75%). Among those tested, 29/42 patients (69.04%) remained RT-PCR positive on day 5. Based on these findings, molnupiravir treatment in this cohort was not associated with a reduction in mean viral load (MVL) by day 5 of therapy.

Discussion

The study evaluated the effectiveness and safety of molnupiravir in 74 non-hospitalized patients with mild to moderate SARS-CoV-2 infection treated on an outpatient basis at the COVID Hospital Mišeluk, UCCV. The mean patient age was 63.82 ± 23.7 years, with an equal sex distribution, consistent with demographic characteristics reported in other real-world studies evaluating antiviral therapy in high-risk populations [4,13].

Although sex-related differences were not a primary focus of this study, a large study conducted in the USA, involving 308,010 hospitalized patients, demonstrated worse outcomes among male patients, including respiratory failure, mortality, and longer hospital stays [14]. The underlying mechanisms are likely multifactorial, with hormonal influences – particularly the immunomodulatory effects of estrogens – proposed as one contributing factor [15].

The study population consisted of patients at increased risk for disease progression due to age and comorbidities. Overall, 74.32% of patients had at least one comorbidity, with cardiovascular diseases – primarily hypertension – being the most prevalent. This finding aligns with previous reports identifying hypertension, obesity, diabetes mellitus, chronic kidney disease, asthma, and autoimmune disorders as major risk factors for severe COVID-19 [16]. Notably, even among patients without documented comorbidities

(19/74), 10 were older than 60 years, and 9 were over 45, supporting the decision to initiate antiviral therapy in this subgroup, in line with the existing evidence indicating increased hospitalization rates among individuals aged ≥45 years [16].

Most patients involved in the study were vaccinated (62/74, (83.73%)), with predominance of the Sinopharm/BBIBP vaccine administered to 40/62 patients (67.74%). Before the appearance of the Omicron variant of the virus, no studies were conducted involving unvaccinated patients [17]. In the Republic of Serbia, vaccination started in late 2020, and 47.1% of the population were fully vaccinated (3 doses) by the time of this study, according to data from the Institute of Public Health "Dr Milan Jovanović Batut" [1].

According to the national protocol, molnupiravir was administered within three days of symptom onset in the majority of patients, with the exception of four individuals who later required hospitalization and received the drug on the fourth day after symptom onset. Results from a phase III randomized, double-blind clinical trial demonstrated that molnupiravir administration within five days of symptom onset significantly reduced the risk of hospitalization from any cause or death by day 29, which is consistent with our findings [4]. Notably, in our study, patients who progressed to more severe disease received treatment later than those who remained ambulatory, underscoring the importance of early antiviral initiation. These observations support the concept that administering molnupiravir as close as possible to symptom onset may reduce the risk of disease progression.

SARS-CoV-2 infection is known to induce systemic inflammation and immune dysregulation, affecting multiple organ systems [18]. Bilateral pneumonia remains the most common and clinically significant complication. Approximately 15–20% of patients develop severe pneumonia requiring hospitalization and oxygen therapy, while about 5% require mechanical ventilation [19]. In our cohort, 25/74 (34%) patients presented with pneumonia at baseline. After five days of molnupiravir therapy, radiological regression of pneumonia was observed in 8/25 (32%) patients, although this finding did not reach statistical significance ($p = 0.28$). Overall, 5.4% of patients progressed to a more severe form of pneumonia requiring hospitalization and oxygen therapy, and only one patient (1.34%) required mechanical ventilation. These proportions are lower than those reported in populations not treated with antiviral therapy [5,20].

Molnupiravir was generally well tolerated. The most frequently reported adverse effects – nausea, vomiting, diarrhea, and headache – are consistent with previously published data [5]. In our study, nausea was the most common adverse event, reported in 15/22 (68.18%) patients. No serious adverse events were observed, and treatment discontinuation was not required in any patient. Furthermore, no clinically significant changes in laboratory parameters were detected at baseline or on the third day of therapy.

Recent studies further support the potential role of molnupiravir in preventing disease progression in high-risk patients. Gentile et al. demonstrated its effectiveness in reducing progression to severe disease [8], while a Czech study by Pavlik et al. reported reduced mortality with early antiviral administration [21]. Additionally, a large national study including 1,172 patients showed that only four required hospitalization, with Gmizić et al. reporting a 97.9% reduction in hospitalization risk associated with molnupiravir use [22]. Conversely, some studies have yielded neutral results; for example, Yip et al. found no statistically significant difference in hospitalization risk between treated and untreated patients [23]. In our cohort, only four patients required hospitalization, and no fatal outcomes occurred during the 28-day follow-up period.

While a meta-analysis reported a high proportion of patients achieving viral RNA negativity by day 5 [24], and Butler et al. demonstrated shorter recovery times with molnupiravir treatment [25], our findings did not show a significant reduction in viral load by day 5. Among 42 patients who underwent follow-up PCR testing, 29 (69.04%) remained PCR-positive [27,28]. Nevertheless, according to the WHO Clinical Progression Scale, most patients experienced clinical improvement, with complete symptom resolution by day 5 observed in 49/74 cases [11].

Sinha et al. reported a significantly higher rate of clinical improvement in patients receiving molnupiravir compared to placebo (80.8% vs. 32.1%) [26], suggesting that molnupiravir reduces viral load more rapidly than placebo, potentially decreasing SARS-CoV-2 transmissibility.

Conclusion

Molnupiravir represents a valuable therapeutic option for the early outpatient treatment of COVID-19 in patients at increased risk of disease progression. In this real-world cohort, early administration was associated with a low rate of hospitalization, absence of fatal outcomes, and a favorable safety profile. These findings support the role of molnupiravir as part of the therapeutic arsenal against COVID-19.

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