CO162

# MORE Serbia: MOlnupiravir REal world utilization among COVID-19 patients in Serbia

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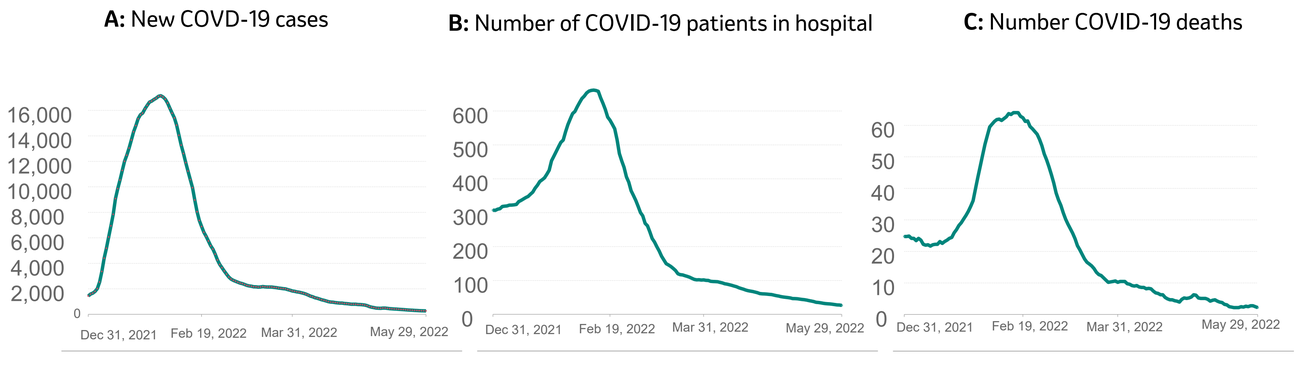
## Background

Molnupiravir (MOV), an oral antiviral treatment against COVID-19 infection, is available in Serbia for treating mild to moderate coronavirus disease 2019 (COVID-19) in adult patients at high risk of progression to severe disease. It is available under an import license which is approved since the end of 2021 following the conclusion of the Government of the Republic of Serbia (СП05:00-566/2021). This study describes the patient profile and health care resource utilization of MOV users in a real-world setting in Serbia.

## Methods

In this chart review study, non-hospitalized adults (≥18 years) with COVID-19 who were treated with MOV between January 1 to April 30, 2022, were included from six outpatient health centers. Patients' characteristics at the time of MOV initiation and clinical outcomes within 28 days after MOV initiation were collected.

**Figure 1**: Confirmed new COVID-19 cases (A), hospitalizations (B) & death (C) per million people in Serbia, January 1 - May 28, 2022.




Adapted from: WHO COVID Dashboard (accessed September 30, 2023: Data retrieved from https://ourworldindata.org/

**Table 1**: Characteristics of patients treated with MOV in Serbia, January 1 - May 28, 2022.

| Parameter | Total (N=1489) |
|---|---|
| **Age group, n (%)** | |
| <60 years old | 758 (50.9%) |
| ≥ 60 years old | 731 (49.1%) |
| **Age (years):** | |
| Mean (SD) | 57.6 (15.2) |
| Median (Q1; Q3) | 59 (46.0; 70.0) |
| Range (min; max) | (19.0; 96.0) |
| **Sex, n (%)** | |
| Male | 634 (42.6%) |
| Female | 855 (57.4%) |
| Other | 0 (0.0%) |
| **BMI group, n (%)** | |
| Underweight | 7 (0.6%) |
| Healthy weight | 380 (30.3%) |
| Overweight | 650 (51.8%) |
| Obese | 217 (17.3%) |
| Missing | 235 |
| **Smoking, n (%)** | |
| Yes | 258 (29.2%) |
| No | 626 (70.8%) |
| Missing | 605 |
| Time between positive COVID-19 test and MOV start, n (%) | |
| 0-2 days | 1474 (99.0%) |
| 3-5 days | 15 (1.0%) |
| Vaccination status, n (%) | |
| No | 454 (30.5%) |
| Yes [1] | 1035 (69.5%) |

[1] Definition of vaccination: patient received at least one vaccination shot.

**Table 2**: Most frequent comorbidities among patients treated with MOV in Serbia study, January 1 - May 28, 2022

| Parameter | Total (N=1489) |
|---|---|
| Comorbidities | |
| Hypertension | 807 (54.2%) |
| Diabetes mellitus, type 1 and type 2 | 268 (18.0%) |
| Obesity | 217 (17.3%) |
| Any respiratory disease | 123 (8.3%) |
| Heart conditions | 117 (7.9%) |
| Asthma | 80 (5.4%) |
| Cancer | 76.(5.1%)) |
| Neurological conditions including dementia | 31 (2.1%) |
| Chronic liver disease | 12 (0.8%) |
| Chronic kidney disease | 8 (0.5%) |
| | |
| Number of comorbidities, n (%) | |
| 0 | 469 (31.5%%) |
| 1 | 478 (32.1%) |
| 2 | 328 (22.0%) |
| 3 | 151 (10.1%) |
| 4 | 48 (3.2%) |
| 5 and more | 15 (1.0%) |
| Multimorbidity | |
| 0-1 comorbid condition | 947 (63.6%) |
| ≥2 comorbid conditions | 542 (36.4%) |

**Table 3**: Most frequent comedications among patients treated with MOV in the Serbia study, January 1 - May 28, 2022

| Parameter | Total (N=1489) |
|---|---|
| 10 most frequent prescribed drug groups by ATC 10 codes[1], | |
| C09 – Agents acting on renin-angiotensin system | 620 (41.6%) |
| C07 – Beta blocking agents | 532 (35.7%) |
| A10 – Drug used in Diabetes | 264 (17.7%) |
| C08 - Calcium channel blockers | 218 (14.6%) |
| C03 - Diuretics | 134 (9.0%) |
| C01 – Cardiac therapy | 112 (7.5%) |
| B01 – Antithrombotic agents | 83 (5.6%) |
| C10 – Lipid modifying agents | 74 (5.0%) |
| G04 – Urologicals | 47 (3.2%) |
| C02 – Antihypertensives (other than above mentioned) | 22 (1.5%) |
| Number of different comedications | |
| ≤ 1 | 697 (46.8%) |
| ≥ 2 | 792 (53.2%) |
| Polypharmacy (≥ 5 comedications, n (%) | |
| Yes | 264 (17.7%) |
| No | 1225 (82.3%) |

[1] Multiresponse question.

## Results

In this analysis, 1,489 patients were included. Mean age was 57.6 (SD: 15.2) years and 57.4 % were female. 36.4% of the patients had co-morbidities, with hypertension (54.2%) being the most common. Out of the total patient population, approximately 69.1% were classified as either overweight (excluding it as a comorbidity factor) or obese. The majority (69.9%) had at least one comedication other than molnupiravir and 17.7% had ≥5 comedications. 69.5% patients received at least one COVID-19 vaccination. In patients <60 years 58.3% of patients were vaccinated (n=758) vs. 81.10% in patients ≥60 years. (p<0.0001).

**Figure 2**: Number of comorbidities stratified by Age (<60 versus ≥60 years)

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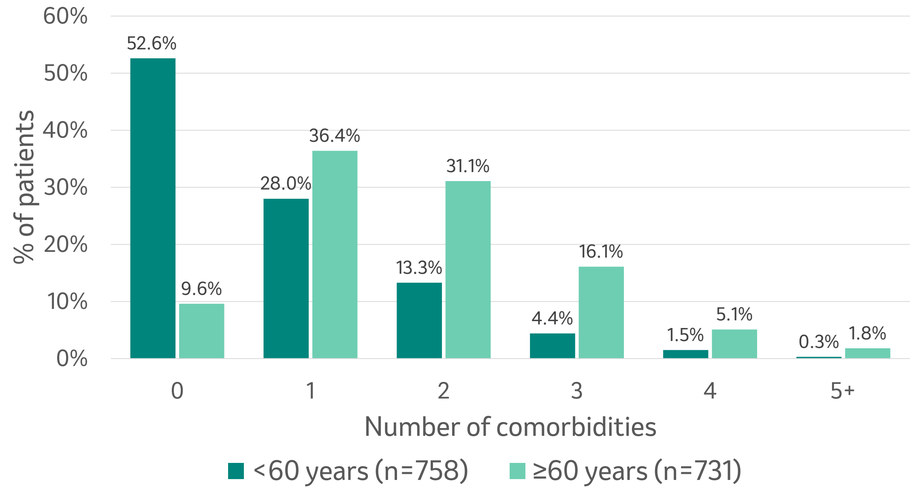
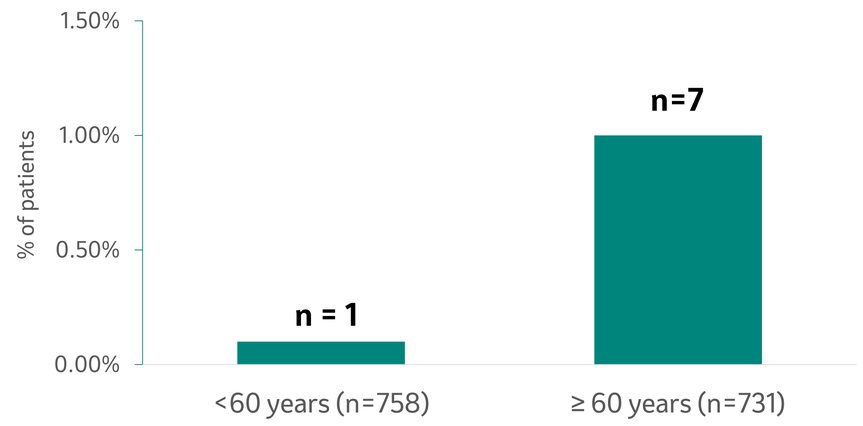



**Figure 3**. All-cause hospitalization stratified by age over 28 days of follow-up after MOV treatment.




Numbers at the top of the bar represent the number of patients experiencing the event

Within 28 days of initiating molnupiravir, 8 (0.5%) patients were hospitalized due to COVID-19. Of the 8 hospitalized patients, 7 were 60 years or older, 2 were admitted to an intensive care unit, and one required mechanical ventilation. The median length of hospital days was 16.0 days (min-max: 4-22 days). Of those hospitalized, 3 (0.7%) were unvaccinated and 5 (0.5%) were vaccinated.

1097 (73.7%) patients had at least one COVID related health care center/outpatient center visit during the follow-up period; on average 1.7 (1.0) visits have been registered. Elderly patients (≥ 60 years) had more all-cause visits (2.6 [2.2]) than the younger patients (2.3 (1.8)). However, COVID-related visits were similar in both groups (1.8 (1.2) vs 1.7 (0.9)).

*Limitation and Bias*

This is a retrospective, single arm patient chart study, where from Jan 01, 2022, consecutive patients meeting inclusion/exclusion criteria were included until the agreed sample size per site was met. Patients with incomplete patient chart (e.g., number of comorbidities and co medications) were not enrolled

## Conclusion

The study investigated the outcomes of patients in Serbia who were treated with MOV in a real-world setting. The average age of the patients was 57 years, and most had fewer than 2 co-morbidities. Over half of the patients received more than two comedications. There were very few hospitalizations and no deaths during the study period. These findings suggest that MOV is a valuable treatment choice, particularly for patients who are not suitable for other COVID-19 therapeutic options.

**Disclosure**

Funding for this study was provided by Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA, known as MSD outside of the USA and Canada..