Predictors of Mortality and Effect of Drug Therapies in Mechanically Ventilated Patients With Coronavirus Disease 2019: A Multicenter Cohort Study

We conducted a multicenter cohort study to determine the effect of drug therapies on survival in mechanically ventilated patients with coronavirus disease 2019. All consecutive adult patients admitted to ICU for coronavirus disease 2019 from March 1, 2020, to April 25, 2020, and under invasive mechanical ventilation for more than 24 hours were included. Out of 2,003 patients hospitalized for coronavirus disease 2019, 361 were admitted to ICU, 257 were ventilated for more than 24 hours, and 247 were included in the study. Simple and multiple time-dependent Cox regression models were used to assess the effects of factors on survival. Methylprednisolone administration during the first week of mechanical ventilation was associated with a decrease in mortality rate from 48% to 34% (p = 0.01). Mortality was significantly associated with older age, higher creatinine, lower lymphocyte count, and mean arterial pressure lower than 70 mm Hg on the day of admission.

To the Editor:

Since the start of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, the World Health Organization (WHO) has advocated for trials to assess the benefit of antiviral treatment, anticytokine drugs, anti-inflammatory drugs, convalescent plasma, and hydroxychloroquine. However, evidence of the efficacy of such strategies is still lacking, except for corticosteroid therapy. In particular, a before-after study suggested a beneficial effect of methylprednisolone use in patients with moderate-to-severe coronavirus disease 2019 (COVID-19) (1). The randomized evaluation of COVID-19 therapy (RECOVERY) trial recently showed dexamethasone resulted in lower 28-day all-cause mortality (3). This meta-analysis observed administration of systemic corticosteroids compared with usual care or placebo was associated with lower 28-day all-cause mortality (3).

Until now, the COVID-19 patients treated with endotracheal intubation and mechanical ventilation have reported mortality rates of 28–81%, depending on patient characteristics (4–8). In Belgian recommendations, before publication of the RECOVERY trial, the use of corticosteroids was left to the discretion of the ICU clinical team. This cohort study aimed to investigate whether drug therapies used against COVID-19 improved survival and to determine predictors of mortality in mechanically ventilated COVID-19 patients.

MATERIALS AND METHODS

This cohort study started at the onset of the pandemic in the area of Liège, Belgium. It was performed in the following 12 hospitals in Wallonia, Belgium: Centre Hospitalier Universitaire de Liège, Centre Hospitalier Régional de Liège, Centre Hospitalier Chrétien de Liege, Centre Hospitalier Régional de Verviers, Centre Hospitalier Chrétien de Herxalle, Centre Hospitalier Régional de Huy, Clinique Notre-Dame de Grâce de Gosselies, Centre Hospitalier Universitaire (Université Catholique de Louvain) of Dinant, Klinik St Josef VoG of St Vith, Centre Hospitalier de Malmedy, Centre Hospitalier du Bois de l’Abbaye of Seraing, and Centre Hospitalier André Renard of Herstal. The Ethics Committee of the University Hospital of Liege (Comité d’éthique hospitalo-universitaire de Liège [707]) reviewed the study and approved it (Reference 2020/194). Due to the retrospective nature of the data collected, no consent from patients was required.

All consecutive adult patients admitted to the participating ICUs for acute respiratory failure due to SARS-CoV-2 pneumonia (diagnosed with a chest tomodensitometry suggestive of COVID-19 and with a positive polymerase chain reaction for SARS-CoV-2 in nasal swab) and mechanically ventilated for at least 24 hours from March 1, 2020, to April 25, 2020 were included. The following data were retrospectively collected and entered in a clinical report form transmitted to the participating ICUs: 1) on ICU admission: admission date, age, gender, body mass index, underlying conditions (smoking, chronic kidney disease, diabetes, and hypertension) urine output, mean arterial pressure, Pao₂/Fio₂ ratio, and laboratory blood values (creatinine, bilirubin, ferritin, C-reactive protein [CRP], d-dimer, platelets count, and lymphocytes count), Sequential Organ Failure Assessment (SOFA) score, and Glasgow Coma Score, 2) during ICU stay: the use of drugs to treat COVID-19 (hydroxychloroquine, azithromycin, and...
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days 0 and 7 of ICU admission. All corticosteroid treatment = 0.85).

mechanical ventilation between steroid and no-steroid group

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for mechanical ventilation was 3 days (IQR, 2–6). There was

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Survivors more frequently received corticosteroids and hydroxy-

pressure and urine output. Nonsurvivors were also more fre-

scores, lower d-dimer values, higher mean arterial pressure, higher

Pao2, and higher Pao2/Fio2 ratio on ICU admission than patients

indications differed between clinicians and comprised: all patients

of Belgium and having no missing patients mitigates selection and

RESULTS

From March 1, 2020, to April 25, 2020, a total of 2,003 adult

patients (87%) were treated with norepinephrine. Four patients

This patient survived. Five patients (0.02%) received antiinterleu-

from day 2 to day 10) but received no corticosteroid treatment.

of COVID-19 if the corticosteroid therapy (methylprednisolone or dexamethasone) was started between day 0 and
day 7 after ICU admission. In particular, corticosteroid use at a

later stage of ICU stay, either for rescue therapy of acute respiratory distress syndrome (ARDS) or prevention of extubation stridor, was

not reported.

Patients were followed during their entire stay in the hospital or

for a minimum of 42 days in the case of prolonged hospital stay. The

primary outcome was the effect of corticosteroid therapy on survival. Secondary outcomes were risk factors for mortality. Quantitative

variables were reported as median and interquartile range (IQR) and compared with a Kruskal-Wallis test. Categorical variables were

expressed as n (%) and compared with a Chi-square test. A Kaplan-

Meier plot was used to describe survival rate. Simple and multiple
time-dependent Cox regression models were used to assess the

effects of corticosteroid therapy and other factors on survival. All

variables that had a p value lower than a critical level of 0.1 were

selected for the multivariate model. A value of p < 0.05 was consid-

ered significant. Missing data were not replaced. Calculations were

performed using SAS (Version 9.4; Analytics Software and Solution, SAS Institute, Cary, NC) and R (Version 3.6.2; R Foundation for

Statistical Computing, Vienna, Austria). All statistical analyses

were done by the Biostatistics and Medico-economic Information Department of the University Hospital of Liege (Liege, Belgium).

RESULTS

From March 1, 2020, to April 25, 2020, a total of 2,003 adult

patients diagnosed with SARS-CoV-2 pneumonia were hospitalized

in the participating hospitals and 361 patients were admitted to

ICU for acute respiratory failure. Of these patients, 257 patients

were mechanically ventilated for more than 24 hours and 247

patients included in the database. Ten patients were not included,

because they were transferred to another hospital (n = 5) or from

another hospital (n = 5) during their ICU stay.

The baseline characteristics of the 247 included patients are

shown in Tables 1 and 2. As opposed to survivors, nonsurvivors

were older and suffered more often from chronic kidney disease

(Table 1). On the day of ICU admission, nonsurvivors had higher

SOFA score and serum creatinine level, and lower mean arterial

pressure and urine output. Nonsurvivors were also more fre-

quently treated with norepinephrine during the first day in ICU.

Survivors more frequently received corticosteroids and hydroxy-

chloroquine. The median time gap between diagnosis and need

for mechanical ventilation was 3 days (IQR, 2–5 d) in survivors

and 2 days (IQR, 1–4 d) in nonsurvivors (p = 0.003). There was

no difference in the median gap between diagnosis and need for

mechanical ventilation between steroid and no-steroid group

(median, 2 d; IQR, 1–4 d vs median, 3 d; IQR, 1–5 d; p = 0.85).

Corticosteroid therapy was started in 58 patients (23%) between
days 0 and 7 of ICU admission. All corticosteroid treatment

regimens were given using methylprednisolone with dosages shown in Table 3. Indications for methylprednisolone admin-

istration differed between clinicians and comprised: all patients

(14 patients), all patients with Pao2/Fio2 ratio less than 150 mm

Hg (36 patients), and between days 5 and 7 if patient condition
did not improve (eight patients). The median time gap between

the diagnosis and steroid use was 3 days (IQR, 2–6). There was no

difference between survivors (median, 3.5; IQR, 2–6) and nonsur-

vivors (median, 2.5; IQR, 1–6) (p = 0.6).

Two hundred and twenty-five patients (91%) received hydroxy-

chlooroquine alone or in combination with methylprednisolone

and/or azithromycin. One patient (0.004%) received antiviral

(remdesivir: 200-mg loading dose IV and 100-mg IV once daily

from day 2 to day 10) but received no corticosteroid treatment.

This patient survived. Five patients (0.02%) received antiinterleu-

kin-6 (Tocilizumab: 164 mg subcutaneously) but no corticosteroid.

Three of these five patients treated by tocilizumab survived. Sixty-

nine patients (28%) needed renal replacement therapy and 215

patients (87%) were treated with norepinephrine. Four patients

(1.6%) were treated with extracorporeal membrane oxygenation.

Patients treated with methylprednisolone had lower SOFA

scores, lower d-dimer values, higher mean arterial pressure, higher

Pao2, and higher Pao2/Fio2 ratio on ICU admission than patients

who did not receive methylprednisolone (Table 2). Using multi-

ple regression, methylprednisolone use, but not hydroxychloro-

quine use, was associated with a lower mortality rate. Mortality

was also significantly associated with older age, higher creatinine,

lower lymphocytes count, and mean arterial pressure lower than

70 mm Hg on the day of ICU admission (Table 1). There was no

difference in CRP and ferritin values between the steroid and no-

steroid groups on the day of admission to the ICU (Table 2). From

the day of admission to the ICU to day 7, CRP values decreased

by 23 mg/L (IQR, −130 to +64 mg/L) in the steroid group and by

1 mg/L (IQR, −78 to +67 mg/L) in the no-steroid group (p = 0.12).

Ferritin values decreased by 443 μg/L (IQR, −503 to −383 μg/L)
in the steroid group and by 0 μg/L (IQR, −511 to +28 μg/L) in the

no-steroid group (p = 0.13).

Overall mortality was 111/247 (45 %). Mortality was 34% (20/58) in patients who received methylprednisolone and 48% (91/189) in patients who did not (adjusted p value = 0.01). The survival probability was 75% by day 23 in patients who received

methylprednisolone versus 75% by day 10 for those who did not.

By day 42, using logistic regression, mortality was lower in

patients treated with methylprednisolone (31% vs 48%; p = 0.028).

DISCUSSION

In this multicenter cohort study of 247 consecutive mechanically

ventilated COVID-19 patients, methylprednisolone therapy was

associated with a lower mortality. Mortality was also significantly

associated with older age and higher severity at ICU admission, as

assessed by mean arterial pressure less than 70 mm Hg, creatinine

values, and lymphocyte count. Mechanically ventilated patients

were chosen, because their definition is objective and their predicted

mortality is high. Including all consecutive patients from a large area

of Belgium and having no missing patients mitigates selection and

attrition bias, whereas mimicking standard care as it occurs.
The characteristics of our cohort were consistent with results observed by previous authors (4–8). These series assessed 37–1,150 mechanically ventilated patients and reported 28–81% mortality rates. In most of these studies, the primary outcome was reported as 28-day all-cause mortality, whereas we followed our patients for their entire hospital stay or for a minimum of 42 days in the case of prolonged hospital stay. The therapies used in our patients were consistent with those used during

### TABLE 1. Baseline Characteristics and Treatment, and Association With Survival in Mechanically Ventilated Patients With Coronavirus Disease 2019

| Variable                                      | All n = 247 | Survivors (n = 136) | Nonsurvivors (n = 111) | Simple Cox–p | Multiple Cox–Adjusted p |
|-----------------------------------------------|------------|---------------------|------------------------|---------------|------------------------|
| Male sex                                      | 172 (69.6) | 95 (69.9)           | 77 (69.4)              | 0.92          | −                     |
| Age (yr)                                      | 65 (57–72) | 63 (55–69)          | 69 (60–77)             | < 0.0001      | < 0.0001               |
| Body mass index (kg/m²)                       | 29 (26–33) | 29 (26–33)          | 30 (26–33)             | 0.88          | −                     |
| Tobacco                                       | 21 (8.5)   | 8 (5.9)             | 13 (11.7)              | 0.05          | 0.07                  |
| Chronic kidney disease                        | 26 (10.5)  | 8 (5.9)             | 18 (16.2)              | 0.0007        | 0.71                  |
| Diabetes                                      | 88 (35.8)  | 48 (35.6)           | 40 (36.0)              | 0.98          | −                     |
| Hypertension                                  | 141 (57.1) | 77 (56.6)           | 64 (57.7)              | 0.71          | −                     |
| Chronic obstructive pulmonary disease         | 32 (13.0)  | 13 (9.6)            | 19 (17.1)              | 0.09          | 0.63                  |
| Cancer                                        | 11 (6.1)   | 5 (3.5)             | 6 (5.3)                | 0.74          | −                     |
| Immune deficiency                             | 16 (6.5)   | 6 (4.4)             | 10 (9.0)               | 0.22          | −                     |
| Sequential Organ Failure Assessment score     | 6 (4–8)    | 5 (3–7)             | 7 (5–9)                | < 0.0001      | 0.27                  |
| Pao2 (mm Hg)                                  | 74 (62–90) | 72 (62–90)          | 75 (64–91)             | 0.95          | −                     |
| FiO2 (%)                                      | 80 (60–90) | 78 (60–90)          | 80 (65–100)            | 0.09          | 0.19                  |
| Pao2/FiO2                                     | 103 (82–132)| 108 (83–140)      | 96 (79–128)            | 0.83          | −                     |
| Platelet count (10⁹/mm³)                     | 207 (156–290)| 209 (160–285)    | 207 (155–293)          | 0.79          | −                     |
| Bilirubin (mg/dL)                             | 0.64 (0.49–0.94)| 0.67 (0.50–0.97)  | 0.60 (0.42–0.93)       | 0.42          | −                     |
| Glasgow Coma Scale = 15                       | 185 (77.4)| 109 (82.6)          | 76 (71.0)              | 0.05          | 0.49                  |
| Creatinine (mg/dL)                            | 1.00 (0.78–1.37)| 0.91 (0.71–1.21) | 1.20 (0.88–1.73)       | < 0.0001      | < 0.0001               |
| Mean arterial pressure < 70 mm Hg            | 89 (36.0)  | 37 (27.2)           | 52 (46.8)              | 0.0004        | 0.01                  |
| Norepinephrine use                            | 128 (51.8) | 58 (42.6)           | 70 (63.1)              | 0.0021        | 0.41                  |
| Urine output (mL/d)                           | 1          | 226 (91.9)          | 132 (97.1)             | 94 (85.5)     | −                     |
| ≥ 500                                         | 226 (91.9) | 132 (97.1)          | 94 (85.5)              | −             | −                     |
| 200–500                                       | 11 (4.5)   | 4 (2.9)             | 7 (6.4)                | −             | −                     |
| ≤ 200                                        | 9 (3.7)    | 0 (0.0)             | 9 (8.2)                | −             | −                     |
| C-reactive protein (mg/L)                     | 175 (108–258)| 172 (107–243)     | 179 (109–261)          | 0.33          | −                     |
| d-dimer (ng/mL)                               | 1,500 (868–3,832)| 1,305 (843–3,190) | 1,938 (990–4,000)      | 0.13          | −                     |
| Lymphocyte count (10⁹/mm³)                    | 0.80 (0.55–1.05)| 0.84 (0.60–1.10)  | 0.75 (0.51–1.02)       | 0.06          | 0.02                  |
| Ferritin (µg/L)                               | 1,185 (582–3,053)| 1,281 (578–2,790) | 1,041 (587–3,196)      | 0.43          | −                     |
| Hydroxychloroquine use                        | 225 (91.1) | 128 (94.1)          | 97 (87.4)              | 0.02          | 0.46                  |
| Azithromycin use                              | 107 (43.3) | 59 (43.4)           | 48 (43.2)              | 0.82          | −                     |
| Corticosteroid use                            | 58 (23.5)  | 38 (27.9)           | 20 (18.0)              | 0.05          | 0.01                  |

*aCox model on log-transformed values.*
first phase of the pandemic. Regular use of hydroxychloroquine in our patients was based on initial observational studies, but its efficacy was not confirmed in a subsequent randomized controlled trial (9). No recommendation prompted adjunctive treatments, because no specific treatment had yet been proven to decrease mortality in critically ill COVID-19 patients on mechanical ventilation. The RECOVERY trial recently demonstrated a beneficial effect of dexamethasone in the most severe patients but was ongoing at the time we treated the patients in Belgium in this study (2).

The beneficial role of methylprednisolone in this study is consistent with what was recently anticipated by Fadel et al (1) in a before-after study, which showed a short course of methylprednisolone that was associated with a reduction in the primary composite end point from 54% to 35%. The primary composite end point in the study by Fadel et al (1) was escalation to ICU from a general

| Table 2. Baseline Characteristics and Treatment in Mechanically Ventilated Patients With Coronavirus Disease 2019 Who Received Methylprednisolone and Those Who Did Not |
|---------------------------------|-------------------------------------------------|-------------------------------------------------|------------------|
|                                  | No Methylprednisolone (n = 189) | Methylprednisolone (n = 58) | p*               |
|                                  | n (%) or Median (Q1–Q3)         | n (%) or Median (Q1–Q3)         |                  |
| Male sex                         | 95 (69.9)                       | 77 (69.4)                       | 0.60             |
| Age (yr)                         | 65 (56–73)                      | 66 (58–70)                      | 0.50             |
| Body mass index (kg/m²)          | 30 (26–33)                      | 28 (26–32)                      | 0.05             |
| Tobacco                          | 19 (10.1)                       | 2 (3.5)                         | 0.12             |
| Chronic kidney disease           | 21 (11.1)                       | 5 (8.6)                         | 0.59             |
| Diabetes                         | 69 (36.7)                       | 19 (32.8)                       | 0.58             |
| Hypertension                     | 109 (57.7)                      | 32 (55.2)                       | 0.74             |
| Chronic obstructive pulmonary disease | 20 (10.6)            | 12 (20.7)                       | 0.05             |
| Cancer                           | 6 (4.9)                         | 5 (8.6)                         | 0.33             |
| Immunodeficiency                 | 12 (6.3)                        | 4 (6.9)                         | 0.88             |
| Sequential Organ Failure Assessment score | 7 (4–8)                        | 5 (3–7)                         | 0.003            |
| PaO₂ (mm Hg)                     | 70 (62–88)                      | 83 (69–101)                     | 0.008            |
| FIO₂ (%)                         | 80 (60–94)                      | 80 (60–90)                      | 0.49             |
| PaO₂/FIO₂                        | 100 (76–128)                    | 109 (91–154)                    | 0.009            |
| Platelet count (10⁹/mm³)         | 207 (156–291)                   | 213 (160–273)                   | 0.78             |
| Bilirubin (mg/dL)                | 0.68 (0.50–0.99)                | 0.59 (0.44–0.88)                | 0.11             |
| Glasgow Coma Scale = 15          | 131 (72.4)                      | 54 (93.1)                       | 0.001            |
| Creatinine (mg/dL)               | 1.02 (0.79–1.40)                | 0.91 (0.75–1.26)                | 0.16             |
| Mean arterial pressure < 70 mm Hg| 59 (31.2)                      | 30 (51.7)                       | 0.004            |
| Norepinephrine use               | 101 (53.4)                      | 27 (46.6)                       | 0.36             |
| Urine output (mL/d)              |                                  |                                |                  |
| ≥ 500                            | 172 (91.5)                      | 54 (93.1)                       | 0.91             |
| 200–500                          | 9 (4.8)                         | 2 (3.4)                         |                  |
| ≤ 200                            | 7 (3.7)                         | 2 (3.4)                         |                  |
| C-reactive protein (mg/L)        | 179 (108–259)                   | 165 (109–236)                   | 0.80             |
| D-dimer (ng/mL)                  | 1,635 (1,004–4,000)             | 990 (599–2,239)                 | 0.01             |
| Lymphocyte count (10⁹/mm³)       | 0.78 (0.55–1.07)                | 0.82 (0.51–1.03)                | 0.81             |
| Ferritin (µg/L)                  | 1,233 (562–3,196)               | 1,132 (720–1,779)               | 0.62             |
| Hydroxychloroquine use           | 171 (90.5)                      | 54 (93.1)                       | 0.54             |
| Azithromycin use                 | 88 (46.6)                       | 19 (32.8)                       | 0.06             |

*p value of Kruskal-Wallis or χ² test.
In our cohort, the methylprednisolone dosage was similar, ranging from 40 mg every 12 hours during 5 days. In a cohort of 247 unselected, sequential patients with SARS-CoV-2 pneumonia treated with mechanical ventilation, we observed mortality as high as 45%. Within this cohort, methylprednisolone therapy was independently associated with a lower mortality rate of 34%. Our results provide additional evidence to support the use of corticosteroids in COVID-19 patients. As these results are consistent with those obtained with dexamethasone, the choice of the optimal molecule, dosage, and treatment duration requires additional trials.

The authors have disclosed that they do not have any potential conflicts of interest.

**TABLE 3. Methylprednisolone Dosage and Duration of Treatment Used in Mechanically Ventilated Coronavirus Disease 2019 Patients**

| Number of patients (n = 58) | Dosage | Duration (d) |
|----------------------------|--------|--------------|
| 36                         | Methylprednisolone 40 mg/12 hr (5 d) and 40 mg/d (5 d) | 10            |
| 9                          | Methylprednisolone 40 mg/d | 10            |
| 8                          | Methylprednisolone 2 mg/kg/d (7 d), 1 mg/kg/d (5 d), and 0.5 mg/kg/d (5 d) | 17            |
| 2                          | Methylprednisolone 40 mg/d | 5             |
| 2                          | Methylprednisolone 1 mg/kg/d | 7             |
| 1                          | Methylprednisolone 1.5 mg/kg/d (3 d), 0.5 mg/kg (2 d), 0.2 mg/kg (2 d), and 0.1 mg/kg (3 d) | 10            |

Although many countries have now adopted the use of dexamethasone for patients receiving either mechanical ventilation or oxygen alone, our results suggest other steroids, such as methylprednisolone, may have a similar or potentially better effect. We believe our results and those of REACT trial support a continuing search for the best molecule among steroids, as well as to determine the optimal dosage and duration of therapy (3). Since there was no evidence that high dose of corticosteroid use was associated with greater benefit than a lower dose of corticosteroid, we suggest a low-dose regimen of dexamethasone (6 mg/d) or a low-weight-based dose of methylprednisolone (0.5 mg/kg/d) during 10 days in COVID-19 patients.

Our study has several limitations. First, it was a retrospective analysis of the cohort due to the rapidity of occurrence of COVID-19 in Belgium and Wallonia. This rate of spread precluded the possibility to make therapy protocols and data assessment homogeneous. As most patients were still in the hospital when data collection started, our approach resulted in very few missing data, and all patients were consistently treated according to conventional intensive care guidelines and in accordance with international guidelines at the time. Second, the study was performed in one part of Belgium (Wallonia) and our results may not be applicable to other regions or countries. However, it is a multicenter study, and we estimate that our hospitals did not suffer shortages of human or material resources, as suggested in several other western countries, which could ameliorate this issue. Third, at the time of the study, there were no required guidelines for specific treatments or protocols for COVID-19. Thus, the practice and approach in caring for these patients could be different from other regions of the world, potentially reducing the external validity of our results. Fourth, due to the lack of consensus about the use of corticosteroid at the beginning of the pandemic, only 23% of patients received corticosteroids with no consistency in steroid use or dosage. These patients were overall less sick at the time of ICU admission than the other cohort. This difference has been considered by using multiple regression analysis in our statistical analysis.

**CONCLUSIONS**

In a cohort of 247 unselected, sequential patients with SARS-CoV-2 pneumonia treated with mechanical ventilation, we observed mortality as high as 45%. Within this cohort, methylprednisolone therapy was independently associated with a lower mortality rate of 34%. Our results provide additional evidence to support the use of corticosteroids in COVID-19 patients. As these results are consistent with those obtained with dexamethasone, the choice of the optimal molecule, dosage, and treatment duration requires additional trials.

The authors have disclosed that they do not have any potential conflicts of interest.

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