Servicio de Farmacia

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BARICITINIB AGAINST SEVERE COVID-19: EFFECTIVENESS AND SAFETY IN HOSPITAL CARE

La Fe Hospital Universitari i Politècnic

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Immunosuppressive agents

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Background and Importance

Baricitinib

Off-label used for COVID19 due to potential role in:

- Systemic inflammation
- Lung damage
- Immune response
- Viral endocytosis

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Aim and Objectives

To analyse the effectiveness and safety of baricitinib for severe COVID-19 in hospitalized patients

Material and methods

- Observational
- Retrospective
- Tertiary hospital
- Multidisciplinary
- Severe COVID19
- Single-center

Inclusion criteria

Adult patients Baricitinib 2-4 mg /24h, 3-4 days

Other COVID-19 treatments were allowed

Variables collected

- Age
- Sex
- Drugs during admission
- Analytical parameters
- Admission period
- **Time to recovery**
- Adverse events
- Overall survival

Clinical improvement → Difference in values on a 1-8 scale of clinical status during admission (from 1=hospital discharge without limitation of activities to 8=death) between day +1 of starting baricitinib and day +14.

Data → Hospital electronic prescription program, Electronic medical record

Statistical analysis → SPSS® v.25 expressing the variables as frequencies, medians with interquartile ranges (IQR) and the Wilcoxon test for p values.

Patients Day 1 Receiving Baricitinib	
Characteristic	Patients
Baricitinib (N = 43)	
< 40 yr	3 (7%)
40–59 yr	11 (26%)
60–79 yr	19 (44%)
≥80 yr	10 (23%)
Male — no.	30 (70%)
Hypertension	22 (51%)
Heart disease	12 (28%)
Respiratory disease	6 (14%)
Days with baricitinib	6 (5-7)
Initial eight-category ordinal scale	6 (6-4)
Analytical parameters improvement day 1 → day 14 (p<0,05)	
Interleukin (IL)-6	-50.7 pg/ml
C-reactive protein	-86.4 mg/l
Serum ferritin	-159.0 ng/ml
Lymphocyte count	+0.41x10³/mm³
Platelets	+51.0x10³/mm³
D-Dimers	-347 ng/ml

Results

49 patients were administered baricitinib

→ n = 6 were excluded
→4 baricit. only 1 day
→2 baricit. only 2 days

43 patients were finally included in the study

⚠ Overall survival → 100%
No adverse event was found

Drugs during admission — nº (%).	
Azithromycin	42 (98%)
Ceftriaxone	36 (84%)
Other antibiotic agent	19 (44%)
Chloroquine or hydroxychloroquine	42 (98%)
Corticosteroids	36 (84%)
Tocilizumab	8 (19%)
Convalescent plasma	2 (5%)
Colchicine	1 (2%)

Outcomes Overall and According to Score on the Ordinal Scale

N = 43	Overall	Initial 8-category scale		
		6	5	4
Clinical improvement**	3 (1-4) p<0.01*	3 (2-4)	2 (1-2)	2 (1-2)
Overall survival at day 14	43 (100)	23 (53)	12 (28)	8 (19)
Time to recovery in days**	12 (9-25)	20 (14-31)	18 (13-34)	23 (15-29)
8-category ordinal scale at day 14	3 (2-4)	23 (53)	12 (28)	8 (19)
1 points	6 (14)	3 (7)	1 (2)	2 (5)
2 points	20 (47)	10 (23)	7 (16)	3 (7)
3 points	3 (7)	1 (2)	0 (0)	2 (5)
4 points	8 (19)	3 (7)	4 (9)	1 (2)
5 points	3 (7)	3 (7)	0 (0)	0 (0)
6 points	3 (7)	3 (7)	0 (0)	0 (0)
7, 8 points	0 (0)	0 (0)	0 (0)	0 (0)

Data are median (interquartile range, IQR) , n (%), or n/N (%).

- Eight-category ordinal scale are:
1, not hospitalized, no limitations of activities
2, not hospitalized, limitation of activities, home oxygen requirement, or both
3, hospitalized, just for infection-control reasons)
4, hospitalized, not requiring supplemental oxygen but requiring ongoing medical care
5, hospitalized, requiring any supplemental oxygen
6, hospitalized, requiring non-invasive ventilation or use of high-flow oxygen devices
7, hospitalized, receiving invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). 8, death.

Time to recovery → *nº days to reach categories 1 or 2 on the eight-category scale*

Conclusion and Relevance

Patients treated with baricitinib for COVID-19 in our study presented statistically significant clinical and analytical improvement without relevant adverse events. The results of ongoing clinical trials will show more light on its efficacy and safety in treating COVID-19