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Original Research Article

EFFECTIVENESS AND SAFETY OF BARICITINIB IN ADDITION TO STANDARD OF CARE (SOC) IN PATIENTS HOSPITALIZED WITH COVID-19: A RETROSPECTIVE STUDY

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ABSTRACT

Background: Baricitinib, an oral Janus-kinase inhibitor, received Emergency Use Authorization for the treatment of COVID-19. This retrospective, single-arm study evaluates the effectiveness and safety of baricitinib in preventing disease progression and reducing mortality in hospitalized patients infected with SARS-CoV-2.

Materials and methods: Data were collected from 60 patients hospitalized with confirmed COVID-19 who received baricitinib therapy between January 2021 and December 2021. Among these, 40% were elderly and 80% had underlying co-morbidities.

Results: Based on the World health Organization (WHO) 10-point clinical progression scale, 63.3% of patients presented with moderate disease (score 4-5), of whom 86.8% recovered, and 84.2% demonstrated prevention in progression to severe disease. In patients with severe disease (score 6-9), who constituted 36.7% of the cohort, 59.1% showed clinical recovery. Notably, no significant adverse effects attributable to baricitinib were observed during the treatment course.

Conclusion: The study findings suggest that baricitinib, when used in conjunction with the standard of care (SOC), is an effective and safe therapeutic option particularly for patients with moderate COVID-19 infection by reducing disease progression and enhancing recovery rates.

Keywords: Baricitinib, Janus-kinase (JAK) Inhibitor, Covid 19.

INTRODUCTION

The pandemic with COVID-19 has had an impact on around 178 million people globally and resulted in more than 30 lakh deaths.[1] The disease severity is caused by a uncontrolled inflammatory reaction and managing this hyper-inflammatory condition may helps in improving the outcomes.[2]

An oral Janus-kinase inhibitor is Baricitinib, which is indicated in rheumatoid arthritis as an anti-inflammatory agent. It also links to (AAK1) AP2 protein-kinase 1 and also to cyclin-G-kinase (GAK). At therapeutic levels, plasma concentration of baricitinib is sufficient to block these kinases, reducing both viral entry and inflammation pertaining to COVID-19.[3] The US Food and Drug-Administration (FDA) and the Indian regulatory that is Central Drugs Standard Control-Organisation (CDSCO) provided the emergency use authorization for Baricitinib in medical management of COVID-19. Data from Adaptive COVID-19 Treatment Trial2 (ACTT-2) showed the use of baricitinib improved hospitilized patient outcomes.[4] COV-BARRIER and RECOVERY trials demonstrated mortality benefits with usage of baricitinib on comparison with the standard of care.[5,6]

To our knowledge, very few studies in India have studied and published the effect of baricitinib on the Indian population. We intend to study if baricitinib with Standard of Care (SOC) is effective in COVID-

19. Study objective was to understand the effectiveness and safety with the combine use of baricitinib and SOC to prevent progressive disease and hospitalized patient's mortality while COVID-19 infection.

MATERIALS AND METHODS

This retrospective, single-arm, observational study was conducted at a tertiary care hospital following approval from the Institutional Ethics Committee. Data were collected retrospectively from the medical records of hospitalized COVID-19 patients who received baricitinib therapy in addition to standard of care (SOC), between January 2021 until December 2021.

Inclusion Criteria

- Hospitalized patients aged 18 years or older
- Laboratory-confirmed SARS-CoV-2 infection via RT-PCR or consistent radiological findings
- Moderate to severe COVID-19
- Administration of baricitinib as part of treatment

Exclusion Criteria

- Active or latent tuberculosis (TB)
- Patients receiving cytotoxic or other biologic therapies (e.g., Tocilizumab, interferons)

Data Collection

A total of 60 patients were included. Data were extracted using a structured data collection form from the hospital's electronic medical records. The following parameters were recorded:

- Demographic details (age, sex)
- Presence of comorbidities
- Clinical presentation and vital signs
- Medication history and baricitinib dosing
- Laboratory values and inflammatory markers
- Microbiological reports
- Radiological imaging (chest X-ray and HRCT thorax)
- Oxygen supplementation status and need for ventilatory support
- Length of hospital stay and ICU transfer rates
- Adverse drug reactions during baricitinib therapy

COVID-19 Severity Scoring

The World Health Organization (WHO) 10-point Ordinal Scale was used to assess disease severity at the time of admission, during hospitalization, and at discharge. The scale is as follows:

- Score 0: Uninfected
- Score 1: Asymptomatic
- Score 2: Symptomatic, independent
- Score 3: Symptomatic, requiring assistance
- Score 4: Hospitalized, no oxygen therapy
- Score 5: Hospitalized, requiring oxygen by mask/nasal prongs
- Score 6: Hospitalized, requiring high-flow oxygen or non-invasive ventilation
- Score 7: Hospitalized, requiring intubation and mechanical ventilation
- Score 8: Hospitalized, requiring vasopressors or renal replacement therapy or ECMO
- Score 9: As above with higher doses of vasopressors or multiple organ support
- Score 10: Death

Standard of Care (SOC)

All patients received SOC treatment as per institutional protocol, which included:

- Intravenous corticosteroids (Dexamethasone or Methylprednisolone)
- Anticoagulants (Enoxaparin or Unfractionated Heparin)
- Intravenous Remdesivir for patients with moderate to severe pneumonia (SpO_2 <94%)

Statistical Analysis: Descriptive statistics (mean, standard deviation, and proportions) were used for quantitative and categorical variables. The Chi-square test was employed to assess associations between categorical variables and outcomes, including mortality. Logistic regression analysis was performed to estimate crude and adjusted risk ratios with 95% confidence intervals. A p-value <0.05 was considered statistically significant. All statistical analyses were carried out using IBM SPSS Statistics for Windows, Version 24.0.

RESULTS

During this study period, sixty patients already treated with baricitinib. Median age was 55 years. Co-morbidities were observed in 80% of the patients, with diabetes (36.7%), hypertension (35%), and Obesity (30%) being the most common [Table 1].

Table 1: Baseline demographic data expressed as percentages and Mean+SD.

Demogrpahic variable	Total cases (n=60)		Mean+SD
	Frequency	percentage	
Age (In years)			
<45	16	26.7%	55.50±14.09
45-60	20	33.3%	
>=60	24	40%	
Gender			
Male	38	63.33%	-
Female	22	36.66%	
BMI (Kg/m2) (n=59)			
<25	17	28.3%	27.592±4.5
25-30	24	40%	
>=30	18	30%	
Comorbidities			
No	12	20%	-
Yes	48	80%	

Associate complications			
Diabetes Mellitus	22	36.66%	-
Hypertension	21	35%	
Ischemic heart disease	4	7.25%	
Chronic kidney disease	1	1.6%	

The average length of hospital stay is 13.7 days. It is seen that 93.3% of the patients required ICU admission, of which 68.3% recovered. On an average 12.96 Days stay in an intensive-care unit.

Improvements with baricitinib for weaning off supplemental oxygenation and mortality are in patients in categories 0, 1, 2, and 3. The outcomes were poor for patients with NIV and MV.

The outcomes on the WHO severity scale, patients with moderate severity (63.3%) recovered better when compared with severe disease (59.1%). Of the 38 (63.3%) patients admitted with moderate severity (4-5), 86.8% (33) recovered, 13.2% (5) died, improvement in severity to mild/ asymptomatic was seen in 78.9% (30), and Prevention in progression to severe disease was seen in 84.2% (32) patients. In 22 (36.7%) patients admitted with a severe severity (6-9), prevention of mortality was seen in 59.1 % (13) while 40.9% (9) died [Table 2].

Table 2: Clinical Outcomes in Patients Administered Baricitinib.

Clinical outcomes	Total patient number (n-60)	Patients who recovered and were discharged	Patients who died
Length of hospitalisation	13.7% (60)	11.84% (46)	20.35% (14)
Patients requiring ICU support	93.33% (56)	68.33% (41)	25.45% (14)
Length of ICU stay	12.96 (55)	10.51 (41)	20.14 (14)
Supplemental oxygen requirement on admission			
0- No supplemental oxygenation, room air	33.33%(20)	85% (17)	15% (3)
1- Oxygen through nasal cannula,	33.33% (20)	80% (18)	10% (2)
2- High concentration oxygen mask	21.67% (13)	61.5% (8)	38.5% (5)
3- Non-invasive ventilation,	8.3% (5)	60% (3)	40% (2)
4- mechanical ventilation,	3.3% (2)	-	100%(2)
HO severity Scale			
4-5 (Moderate)	63.3% (38)	86.8% (33)	13.15% (5)
		Mild:78.9% (30)	
		Moderate: 5.26% (2)	
		Severe: 2.63% (1)	
4-5 (Moderate)	63.3% (38)	86.8% (33)	13.15% (5)
		Mild:78.9% (30)	
		Moderate: 5.26% (2)	
		Severe: 2.63% (1)	

Significant variables associated with mortality are BMI, Co-morbidities, WHO severity scoring, and oxygen requirement (Sp02). Obese category 3 had an eight times higher risk, co-morbidities, and WHO severity-severe (6-9) on admission had a six times higher risk of mortality [Table 3].

Table 3: Risk estimates of Mortality with variables expressed in odds ratio.

Variable	Category	Crude odds ratios (COR)	P value	Adjusted odds ratio (AOR)	P value
Gender	Female	1.0		-	-
	Male	1.61(0.437-5.909)	0.475		
BMI	<25	1.0		-	-
	25-30	1.07 (0.159-7.221)	0.943	1.598(0.19-12.99)	0.661
	>30	6.0 (1.049-34.317)	0.044	7.991(1.13-56.47)	0.037
Co-morbidity	No	1.0	-	-	-
	Yes	3.55 (0.969-13.03)	0.056	5.906(1.13-30.76)	0.035
Age	<45	1.0		-	-
	45-60	6.429 (0.685-60.313)	0.103		
	>60	6.176 (0.679-56.153)	0.106		
Duration of hospital stay	<7 days	1			
	≥7 days	3.162 (0.385-27.432)	0.296		
ICU stay	<7 days	1			
	≥7 days	5.687 (0.677-47.798)	0.109		
WHO Severity on Admission	Moderate	1			
	Severe	4.569 (1.286-16.233)	0.019	6.075(1.27-28.92)	0.023
Oxygen support	No supplemental oxygen	1	-	-	-
	Nasal cannula	0.63 (0.093-4.244)	0.635		
	High concentration oxygen mask	3.542 (0.612-18.623)	0.135		
	Non-invasive ventilation and mechanical ventilation	7.556 (1.09-52.357)	0.041		

*P value <0.05% -significant

DISCUSSION

The effects and safety with usage of baricitinib in individuals with moderate severity to severe infections of COVID 19 are studied in our retrospective analysis. Baricitinib is currently recommended as an adjunct to steroids in moderate severity to severe, or critical infections of Covid19.[8] This study population was 40% elderly (>60 years), 63.33% male, and 80% had co-morbidities. On the WHO severity scale of 10, 63.3% of patients had moderate severity (4-5), and 36.7% had severe severity (6–9). 91.66% of the patients required ICU support, of which 68.33% recovered. 83.3% of patients required supplemental oxygen, of which 60% recovered. Prevention in the progression of disease (84.2%) and mortality benefit (86.8%) are seen in moderate severity (WHO-4 and 5). Cantini et al., Selvaraj et alreported beneficial effects of baricitinib on clinical improvement in moderately affected COVID-19 patients. [9,10] The findings are comparable to those of the COV-barrier study, which found a reduction in the mortality for less critically ill hospitalised patients.[6]

Improvement on clinical status and mortality benefit was lower (59.1%) in patients with severe disease as also seen in some studies by Ely et al and Gomez et al.[11,12] Similar levels of mortality, were seen in critically ill patients (45%), particularly in older patients (51-60) and in those requiring invasive mechanical ventilation as in our study.[13]

A higher incidence of comorbidity (80%) may be responsible for the poorer outcomes in the severe group. Patients with comorbidities observed to have a increase risk of not good clinical outcome, which is consistent in our findings.[14] Obesity has an eightfold increase in the risk of mortality in our sample, which is consistent with earlier studies in which obesity is linked to increased disease severity and death.[15] As in our study, no major side effects are seen when baricitinib is combined with SOC.[4] High-dose baricitinib is found to be well tolerated in terms of adverse effects in patient populations.[16]

CONCLUSION

In COVID-19 patients, baricitinib added to the SOC is a safe and effective therapy, particularly in those with moderate severity. It prevents the increase in severity of covid-19 from moderate. However, obesity is linked to an eight-fold increased risk of mortality. Efficacy needs to be further confirmed in large randomized controlled clinical trials.

Limitations of the study: Some of our study's limitations are that it is a single-center study with a smaller patient population with greater comorbidities. Other limitations are the retrospective nature of the data.

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