

## Purpose:

- The purpose of this study was to evaluate patient characteristics and efficacy of tocilizumab (TOCI) versus baricitinib (BARI) for the treatment of severe COVID-19 infection

## Background:

- Evaluations of new treatment options to reduce mortality in hospitalized patients with COVID-19 are urgently needed to reduce the high frequency of deaths that persists despite improvements in standards of care<sup>1</sup>
- The RECOVERY trial found that TOCI significantly reduced the chance of progressing to IMV or death, increased the probability of discharge within 28 days, and reduced 28-day mortality<sup>2</sup>
- The COV-BARRIER provided evidence that BARI plus standard of care (dexamethasone and remdesivir) showed no significant reduction in frequency of disease progression, but was associated with reduced mortality in hospitalized patients with COVID-19<sup>1</sup>
- TOCI and BARI have been shown to improve mortality in patients with severe COVID-19 disease however, there is limited comparative data amongst these agents for the treatment of severe COVID-19 disease.

## Methods:

- Study Design: IRB approved retrospective observational chart review of patients with severe COVID-19 disease from September 2020-November 2021 located at Jefferson Health New Jersey, a 656 bed 3-hospital system
- Primary Endpoint: Incidence of all cause inpatient mortality (ACIM) in patients receiving tocilizumab and baricitinib
  - Subgroup analysis: assessment of clinical improvement and progression to IMV between TOCI and BARI
- Secondary Endpoint: Risk factors associated with ACIM
- Inclusion Criteria:  $\geq 18$  years old, supplemental O<sub>2</sub> at beginning of therapy, received at least one dose of treatment, and severe COVID-19 disease (SpO<sub>2</sub>  $\leq 94\%$ , PaO<sub>2</sub>/FiO<sub>2</sub>  $\leq 300$  mmHg, RR  $\geq 30$  breaths/min, lung infiltrates  $\geq 50\%$ )
- Exclusion Criteria: IMV at beginning of therapy
- Patients were then matched based on BMI, age, and severity of hypoxemia at the start of therapy
- Statistical Analysis: Chi Square (primary Endpoint and subgroup analysis), multi-logistic regression (secondary endpoint)

## Results

Table 1: Baseline demographics and clinical characteristics

	Baricitinib	Tocilizumab
N (identical)	87	87
Age, median (range)	65 (28-91)	64 (30-90)
Gender, M	65%	57%
BMI $\geq 30$ kg/m <sup>2</sup>	52%	52%
ICU admission, Y	54%	46%
Time from symptom to presentation, days median (range)	6 (1-28)	7 (1-60)
Time from symptoms to therapy, days median (range)	9 (0-31)	9 (1-63)
Low flow NC at the start of therapy, patients	59%	59%
HFNC at the start of therapy, patients	41%	41%
Length of hospital admission, days median (range)	12 (4-41)	9 (2-34)
CRP at start of therapy, mean ( $\pm$ SD)	8.7 mg/L ( $\pm$ 6.9)	15.2 mg/L ( $\pm$ 7.8)

Table 2: Primary endpoint

	Baricitinib	Tocilizumab	P-value
All cause overall inpatient mortality	33%	22%	0.126
Inpatient mortality based on oxygenation, (primary)			
Low flow O <sub>2</sub>	20%	12%	0.415
High Flow O <sub>2</sub>	53%	36%	0.236

Table 3: Subgroup analysis

	Baricitinib	Tocilizumab	P-value
Clinical improvement (COS $\geq 2$ ) at EOT	22%	44%	0.004
Progressed to IMV, Y	26%	10%	0.01

Figure 1: Secondary endpoint – baricitinib

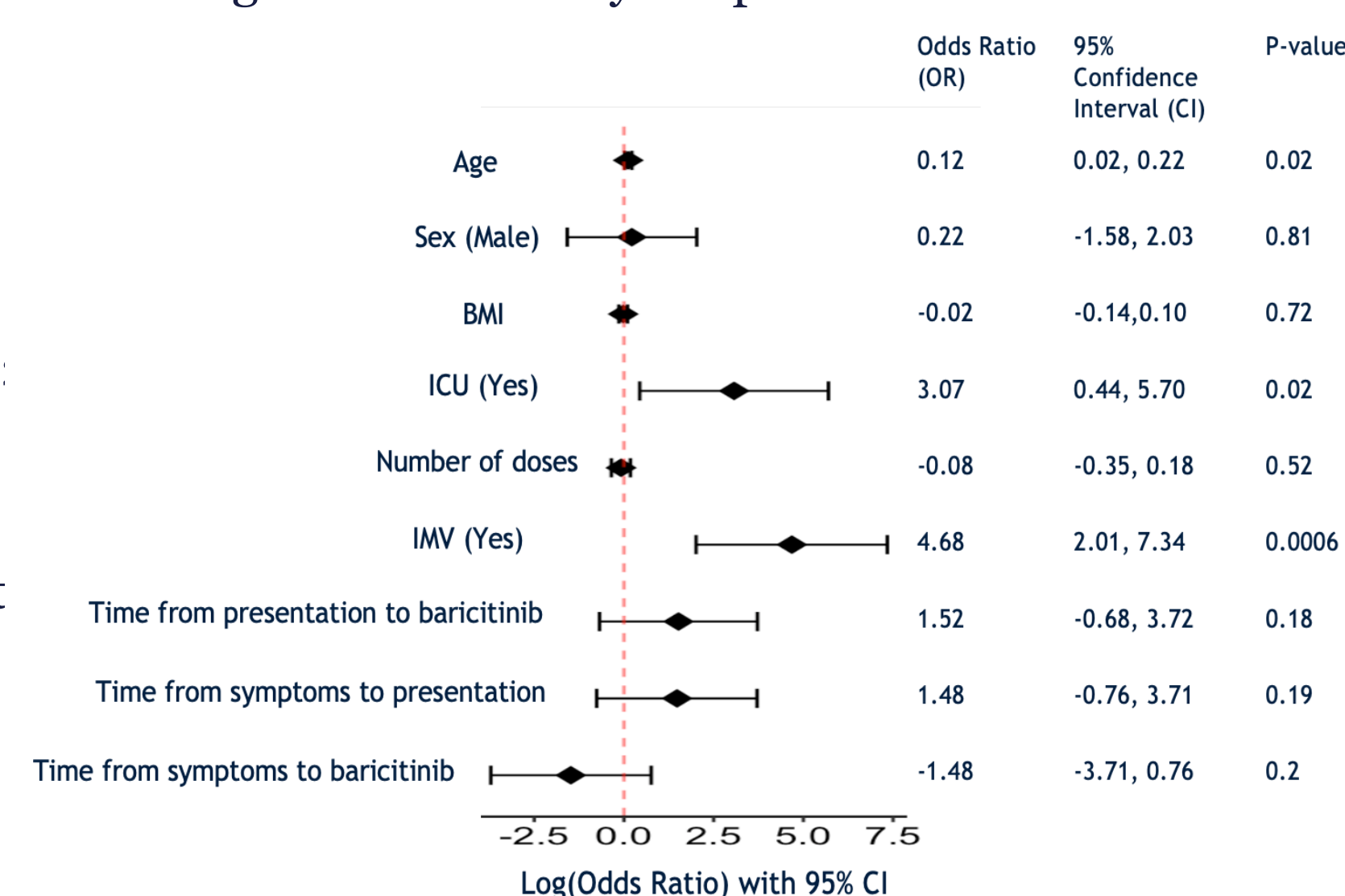
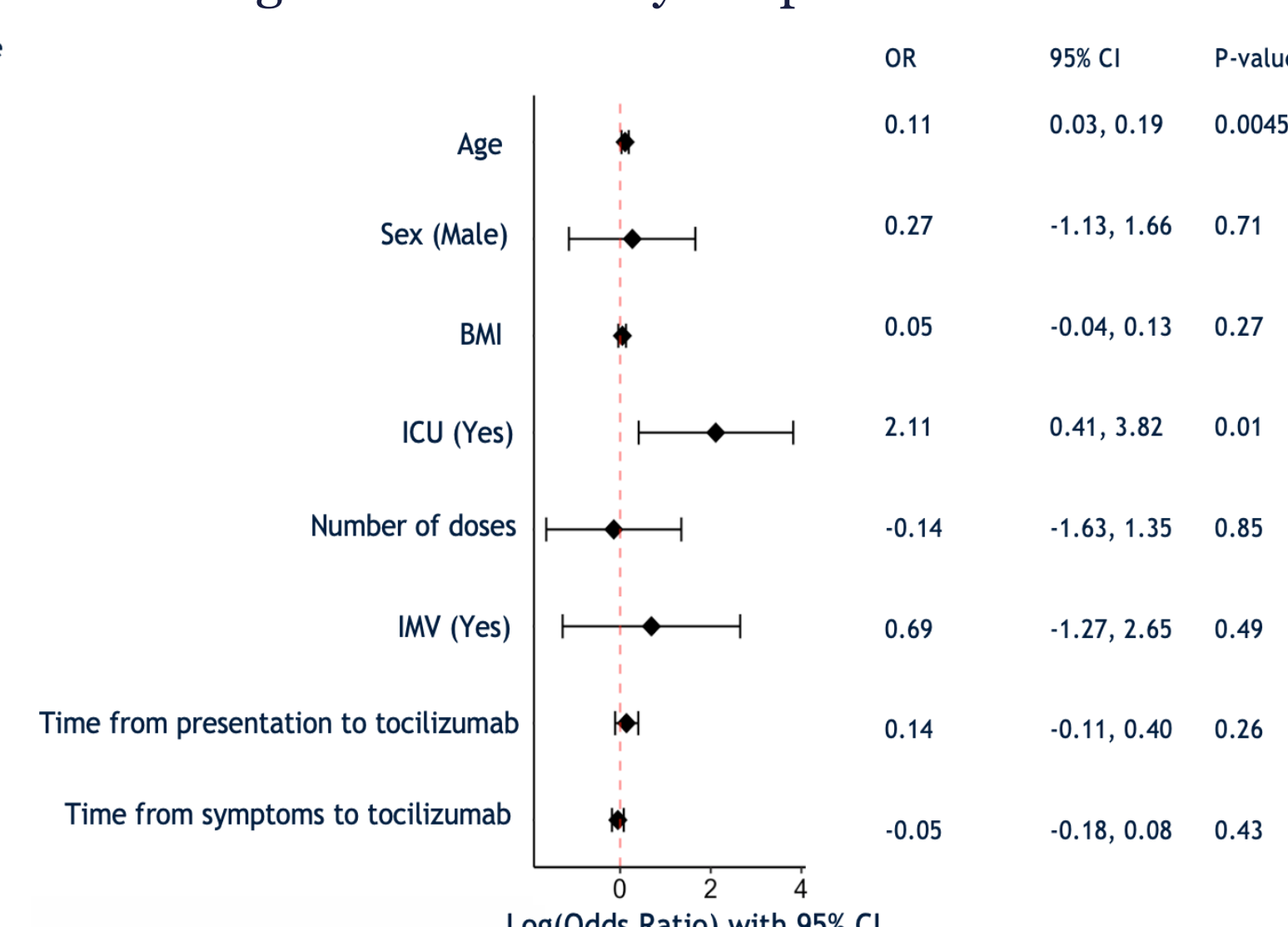
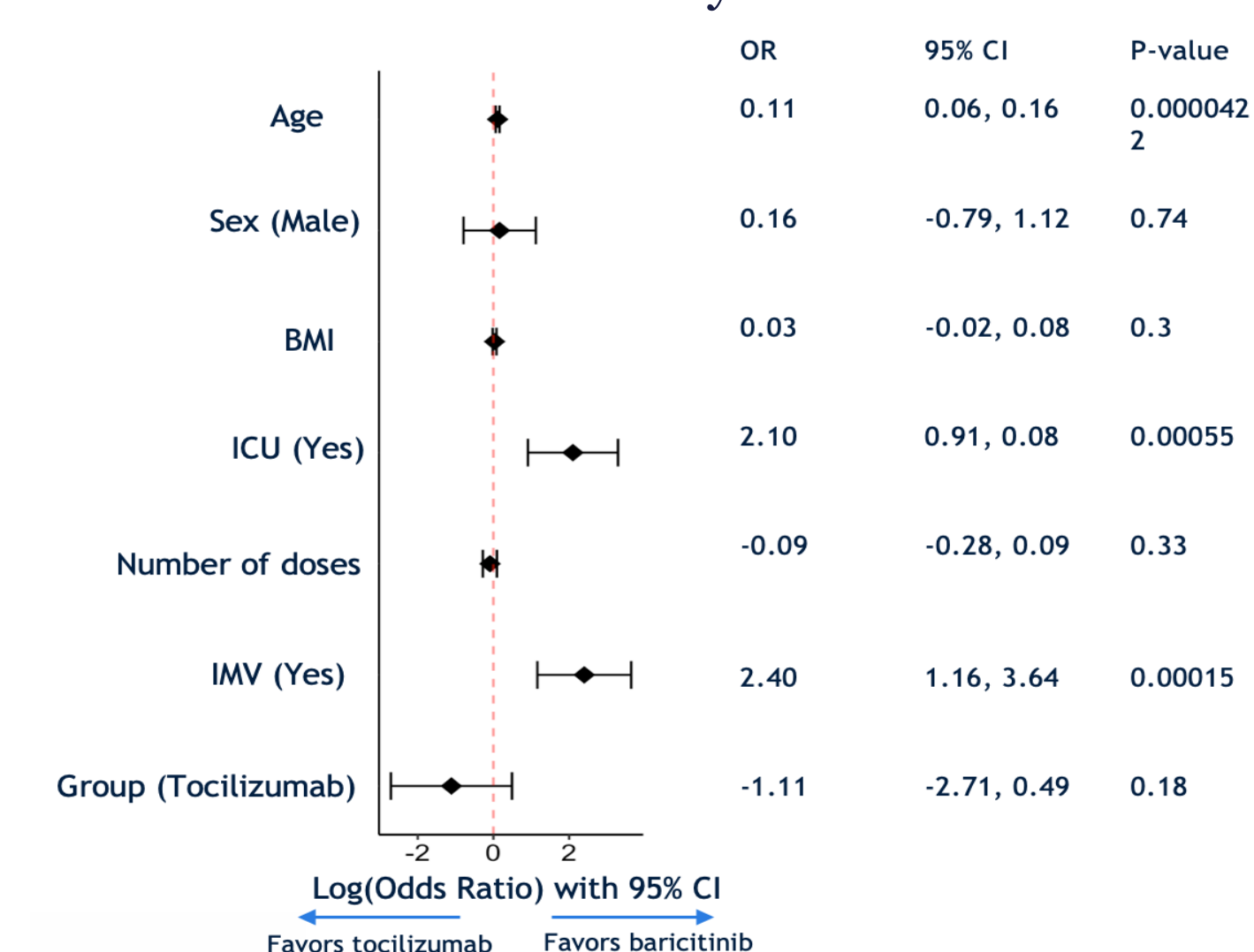


Figure 2: Secondary endpoint – tocilizumab



## Results (continued)

Figure 3: Logistic regression of association mortality with baricitinib and tocilizumab



## Discussion

- Majority of patients included were male, geriatric, and required supplemental oxygenation at the start of therapy
- When patients were matched no difference was seen in all cause inpatient mortality in both treatment groups
- Risk factor associated with high risk of ACIM in both treatment arms was ICU level of care.
- Patients receiving TOCI were more likely to experience clinical improvement, and less likely to progress to IMV in comparison to BARI
- Patients in both treatment arms had higher odds of ACIM when requiring ICU level of care
- When compared to head to head, TOCI lower likelihood of mortality in patients progressing to IMV or required ICU level of care compared to BARI

## Conclusion

- There was no difference in inpatient mortality found between BARI and TOCI treatment arms however, TOCI should be preferred therapy in patients requiring ICU level of care or IMV

## Disclosure

The authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

## Reference

- Marconi VC, Ramanan AV, Bono SD et al. Efficacy and safety of baricitinib for the treatment of hospitalized adults with COVID-19 (COV-BARRIER): A randomized, double-blind, parallel-group, placebo-controlled phase 3 trial. *Lancet Respir Med.* 2021. [e-pub]. [https://doi.org/10.1016/S2213-2600\(21\)00331-3](https://doi.org/10.1016/S2213-2600(21)00331-3)
- RECOVERY Collaborative Group. Tocilizumab in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial. *Lancet.* 2021;397(10285):1637-1645. doi:10.1016/S0140-6736(21)00676-0