The Daily COVID-19 Literature Surveillance Summary

October 21, 2020

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COVID-19 Daily Literature Surveillance

COVID19LST

Bringing you real time, distilled information for guiding best practices during the COVID-19 pandemic

LEVEL OF EVIDENCE

Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or *n*-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or *n*-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non -randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

*** Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.**

**** As always, a systematic review is generally better than an individual study.**

How to cite the Levels of Evidence Table

OCEBM Levels of Evidence Working Group*. "The Oxford 2011 Levels of Evidence".
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EXECUTIVE SUMMARY

Epidemiology

- A 3-patient case series highlights the potential association between COVID-19 and pancreatitis in pediatric patients. The authors report this association based on temporal observations, asserting that clinicians should be aware of COVID-19 as a potential diagnosis in patients with extra-pulmonary presentations such as pancreatitis.

Understanding the Pathology

- A prospective cohort study of PCR-proven or presumed SARS-CoV-2 infected patients at a tertiary care hospital in the Netherlands found that complement factors C3a, C3c and the terminal complement complex (TCC) were elevated in COVID-19 patients sent to the ICU (n=75) compared to non-ICU COVID-19 patients (n=115; $p<0.005$ for C3a and TCC), and more intense complement activation was present in patients that deceased and in those with thromboembolic events.

R&D: Diagnosis & Treatments

- A randomized controlled trial of patients hospitalized with COVID-19 pneumonia (n=126) conducted across 24 hospitals in Italy compared treatment with tocilizumab versus standard therapy and found 28.3% of patients who received tocilizumab worsened in clinical condition within 14 days compared to 27.0% who received standard of care, 3.3% in the tocilizumab group died versus 1.6% in the standard therapy group, and those who received tocilizumab had a higher incidence of adverse events overall than those who received standard therapy.

- A physician from the Division of Infectious Diseases at University of North Carolina at Chapel Hill examined studies on tocilizumab as a treatment for COVID-19 and found two randomized control trials (RTCs) met predefined efficacy thresholds via reduction of mechanical ventilation or death (EMPACTA, 28 day threshold; CORIMUNO-19, 14 day threshold), suggesting that observational studies have demonstrated a mortality benefit but current RCT data do not adequately support efficacy of tocilizumab in COVID-19 treatment and would recommend against routine use.

TABLE OF CONTENTS

CLIMATE

COLLEGE STUDENTS' COMFORT WITH AND INTENTION TO USE SELF-COLLECTION SERVICES FOR STI TESTING

Lindley LL, Sharif AM, Chowdhury T.. J Am Coll Health. 2020 Oct 13:1-10. doi: 10.1080/07448481.2020.1820511. Online ahead of print.
Level of Evidence: 4 - Local non-random sample

BLUF

Investigators from George Mason University, University of Virginia, and University of California San Diego examined college students' perceptions of self-collection services for STI testing through a self-report, online survey (n=434 college students at a large public university in February 2018; Table 1). Most students (88%) indicated that they would be more likely to complete a take-home STI test compared to self-collection in a private room at a student health services clinic (59%; Figure 1). This suggests that self-testing options may increase willingness to test for STIs among college-aged individuals, which is a particularly useful technique during the COIVD-19 pandemic.

ABSTRACT

OBJECTIVE: Sexually transmitted infections (STIs) are at unprecedented levels; yet most college students have never been tested. Offering asymptomatic individuals the option to collect their own samples for STI testing is an effective strategy to increase testing coverage. This study explores students' perceptions of self-collection services. Participants: Four hundred and thirty-four (434) students from a large public university completed an online survey in February 2018. Methods: The cross-sectional survey assessed students' human immunodeficiency virus (HIV)/STI testing behaviors, comfort with self-collection procedures, and intention to use self-collection services if offered on campus. Results: Most students (88%) said they would use self-collection test kits they could take home, followed by self-collection in a private room at student health services (59%). Students were most comfortable with testing procedures involving less human interaction and collecting specimens themselves. Cost, accuracy, confidentiality of tests, and provision of clear "how to" instructions, topped students' concerns. Conclusion: Offering self-collection options may increase STI testing among asymptomatic college students.

Table 1. Characteristics of respondents [a] (n=434). (Table view)

		n	%
Age	18–24 years	316	72.8
	25–29 years	74	17.1
	30+ years	44	10.1
Race	White	269	62.0
	Black/African American	37	8.5
	Asian/Pacific Islander	69	15.9
	American Indian/Alaska Native	3	0.7
	Biracial/Multiracial	31	7.1
	Prefer Not to Answer	12	2.8
	Not listed [b]	10	2.3
Hispanic/Latino(a)	Yes	64	14.7
	No	360	82.9
	Prefer not to answer	9	2.1
International student	Yes	30	6.9
	No	403	92.9
Sex at birth	Male	100	23.0
	Female	333	76.7
Transgender	Yes	8	1.8
	No	425	97.9
Gender identity	Man	96	22.1
	Woman	324	74.7
	Transman	1	0.2
	Genderqueer	8	1.8
	Another identity [c]	4	0.9
Sexual orientation	Heterosexual/straight	306	70.5
	Gay or Lesbian	43	9.9
	Bisexual	41	9.4
	Queer	11	2.5
	Pansexual	8	1.8
	Asexual	7	1.6
	Questioning	5	1.2
	Not listed [d]	5	1.2
	Prefer not to answer	6	1.4
Type of student	Undergraduate	310	71.4
	Graduate/professional	122	28.1
Residence	On campus	151	34.8
	Off campus	283	65.2

[a] Does not include missing responses.
[b] Not listed (Race): nearly all (9/10) identified as Hispanic/Latino.
[c] Another identity (gender identity): agender; masculine; female, non-binary.
[d] Not listed (sexual orientation): demisexual, heteroflexible, mostly straight, and heteroromantic bisexual.

Table 1. Characteristics of respondents (n = 434)

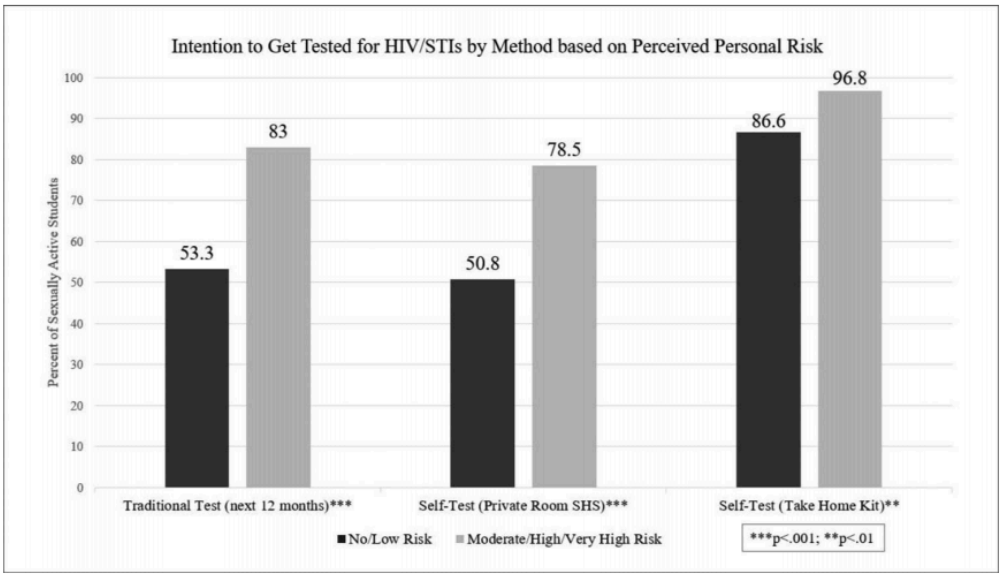


Figure 1. Sexually active students' intention to get tested for HIV/STIs by testing method based on students' perceived personal risk.

PEDIATRICS

PANCREATITIS IN PEDIATRIC PATIENTS WITH COVID-19

Samies NL, Yarbrough A, Boppana S.. J Pediatric Infect Dis Soc. 2020 Oct 19:piaa125. doi: 10.1093/jpids/piaa125. Online ahead of print.
Level of Evidence: 4 - Case-series

BLUF

A 3-patient case series from the Division of Pediatric Infectious Diseases at University of Alabama highlights the potential association between COVID-19 and pancreatitis in pediatric patients. The authors report this association based on temporal observations, asserting that clinicians should be aware of COVID-19 as a potential diagnosis in patients with extra-pulmonary presentations such as pancreatitis.

SUMMARY

The authors present three cases:
1. A 15 year-old obese male presented with epigastric pain, non-bilious and non-bloody emesis, and fever. Abdominal imaging and elevated lipase supported a diagnosis of pancreatitis and further imaging revealed bibasilar ground glass opacities in the lungs. Patient also developed anosmia and ageusia. COVID-19 was ultimately confirmed via RT-PCR and the patient was treated with IV fluids, liquid diet, and pain control then discharged in stable condition 3 days after admission.

2. An 11 year-old male presented with periumbilical pain, poor oral intake, headaches, epistaxis, hematochezia, and fever. Abdominal imaging and elevated lipase supported a diagnosis of pancreatitis and uncomplicated appendicitis. The patient had tested positive for COVID-19 two days prior to admission and tested positive again after admission. Chest X-Ray revealed central interstitial opacities and peribronchial thickening in the lungs, and the patient was treated with IV fluids and a course of piperacillin-tazobactam then discharged in stable condition 4 days after admission.

3. A 16 year-old female with history of pancreatitis presented with epigastric pain radiating to the back, poor oral intake, and fever. Abdominal imaging and elevated lipase supported a diagnosis of pancreatitis. The patient had tested positive for COVID-19 one week prior to admission and tested positive again upon admission. Patient was treated with IV fluids and following resolution of respiratory symptoms was discharged in stable condition 3 days after admission.

COMPLEMENT ACTIVATION IN THE DISEASE COURSE OF COVID-19 AND ITS EFFECTS ON CLINICAL OUTCOMES

de Nooijer AH, Grondman I, Janssen NAF, Netea MG, Willems L, van de Veerdonk FL, Giamarellos-Bourboulis EJ, Toonen EJM, Joosten LAB.. J Infect Dis. 2020 Oct 10:jiaa646. doi: 10.1093/infdis/jiaa646. Online ahead of print.
Level of Evidence: 3 - Cohort study or control arm of randomized trial

BLUF

Physicians from Radboud University Medical Center (Netherlands) and the University of Bonn (Germany), performed a prospective cohort study analyzing the activation of the complement system in PCR-proven or presumed SARS-CoV-2 infected patients at a tertiary care hospital in the Netherlands (March to April 2020). Complement factors C3a, C3c, and the terminal complement complex (TCC) were elevated in COVID-19 patients sent to the ICU (n=75) compared to non-ICU COVID-19 patients (n=115; Figure 3A and C; p less than 0.005 for C3a and TCC). Further, more intense complement activation was present in patients that deceased and in patients with thromboembolic events. These findings suggest a role for complement activation in the immune dysregulation seen in COVID-19 and a possible potential to utilize complement factors for predicting disease severity, although further investigation is needed to confirm this relationship.

ABSTRACT

BACKGROUND: Excessive activation of immune responses in coronavirus disease 2019 (COVID-19) is considered to be related to disease severity, complications and mortality. The complement system is an important component of innate immunity and can stimulate inflammation, but its role in COVID-19 is unknown. METHODS: A prospective, longitudinal, single center study was performed in hospitalized COVID-19 patients. Plasma concentrations of complement factors C3a, C3c, and terminal complement complex (TCC) were assessed at baseline and during hospital admission. In parallel, routine laboratory and clinical parameters were collected from medical files and analyzed. RESULTS: Complement factors C3a, C3c and TCC were significantly increased in plasma of COVID-19 patients compared to healthy controls ($p<0.05$). These complement factors were especially elevated in ICU patients during the entire disease course ($p<0.005$ for C3a and TCC). More intense complement activation was observed in patients that deceased and in patients with thromboembolic events. CONCLUSIONS: COVID-19 patients demonstrate activation of the complement system, which is related to disease severity. This pathway may be involved in the dysregulated pro-inflammatory response associated with increased mortality and thromboembolic complications. Components of the complement system might have potential as prognostic markers for disease severity and as therapeutic targets in COVID-19.

FIGURES

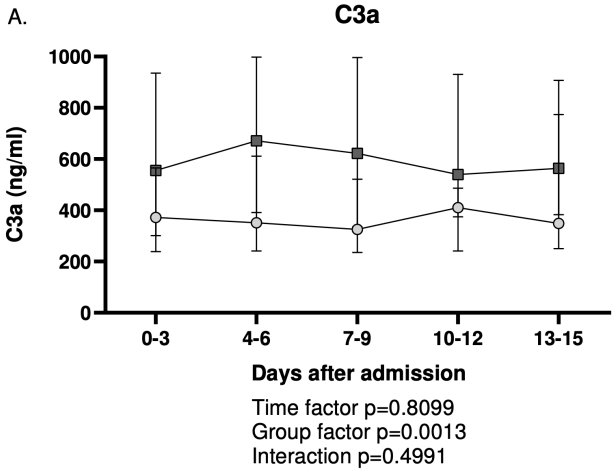


Figure 3A. Concentrations of complement factors in non-ICU and ICU patients with COVID-19 over time. Longitudinal course of C3a (A.) plasma concentration during hospital
admission in non-ICU (n=115) and ICU patients (n=75) with COVID-19. P-values were calculated with general mixed model analyses on log transformed data. Data are presented as median with interquartile range. Abbreviations: ICU, Intensive Care Unit; COVID-19, coronavirus diseases 2019

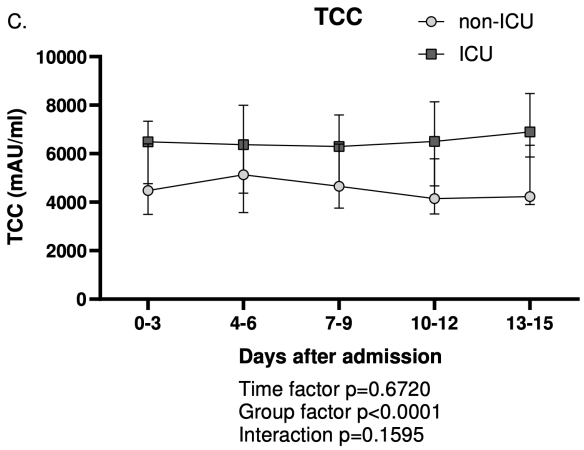


Figure 3C. Concentrations of complement factors in non-ICU and ICU patients with COVID-19 over time. Longitudinal course of TCC (C.) plasma concentration during hospital
admission in non-ICU (n=115) and ICU patients (n=75) with COVID-19. P-values were calculated with general mixed model analyses on log transformed data. Data are presented as median with interquartile range. Abbreviations: ICU, Intensive Care Unit; COVID-19, coronavirus diseases 2019; TCC, terminal complement complex.

EFFECT OF TOCILIZUMAB VS STANDARD CARE ON CLINICAL WORSENING IN PATIENTS HOSPITALIZED WITH COVID-19 PNEUMONIA: A RANDOMIZED CLINICAL TRIAL

Salvarani C, Dolci G, Massari M, Merlo DF, Cavuto S, Savoldi L, Bruzzi P, Boni F, Braglia L, Turrà C, Ballerini PF, Sciascia R, Zammarchi L, Para O, Scotton PG, Inojosa WO, Ravagnani V, Salerno ND, Sainaghi PP, Brignone A, Codeluppi M, Teopompi E, Milesi M, Bertomoro P, Claudio N, Salio M, Falcone M, Cenderello G, Donghi L, Del Bono V, Colombelli PL, Angheben A, Passaro A, Secondo G, Pascale R, Piazza I, Facciolongo N, Costantini M; RCT-TCZ-COVID-19 Study Group.. JAMA Intern Med. 2020 Oct 20. doi: 10.1001/jamainternmed.2020.6615. Online ahead of print.

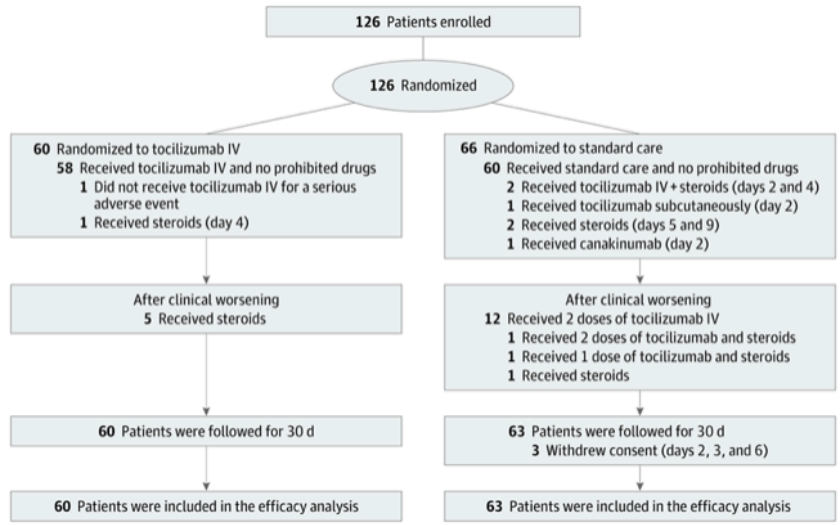
Level of Evidence: 2 - Randomized trial or observational study with dramatic effect

BLUF

A randomized controlled trial of patients hospitalized with COVID-19 pneumonia (n=126; Figure 1) conducted across 24 hospitals in Italy from March 31 to June 11, 2020 compared treatment with tocilizumab versus standard therapy. They found 28.3% of patients who received tocilizumab worsened in clinical condition within 14 days compared to 27.0% who received standard of care, 3.3% in the tocilizumab group died versus 1.6% in the standard therapy group, and those who received tocilizumab had a higher incidence of adverse events overall than those who received standard therapy (Tables 2,3). Authors suggest tocilizumab may not provide additional benefit compared to standard of care for patients with COVID-19, emphasizing a need for further research via blinded randomized control trials.

FIGURES

Figure 1. Flowchart of the Study



IV indicates intravenous.

Table 2. Clinical Outcomes in the Intention-to-Treat Population

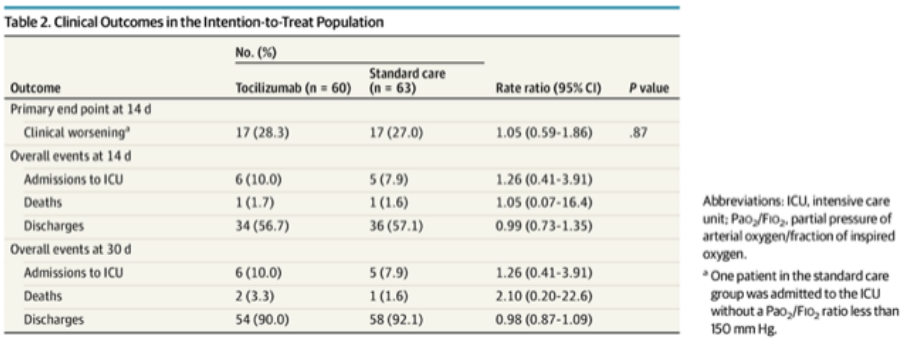


Table 2. Clinical Outcomes in the Intention-to-Treat Population

Outcome	No. (%)		Rate ratio (95% CI)	*P* value
	Tocilizumab (n = 60)	Standard care (n = 63)		
Primary end point at 14 d				
Clinical worsening[a]	17 (28.3)	17 (27.0)	1.05 (0.59-1.86)	.87
Overall events at 14 d				
Admissions to ICU	6 (10.0)	5 (7.9)	1.26 (0.41-3.91)	
Deaths	1 (1.7)	1 (1.6)	1.05 (0.07-16.4)	
Discharges	34 (56.7)	36 (57.1)	0.99 (0.73-1.35)	
Overall events at 30 d				
Admissions to ICU	6 (10.0)	5 (7.9)	1.26 (0.41-3.91)	
Deaths	2 (3.3)	1 (1.6)	2.10 (0.20-22.6)	
Discharges	54 (90.0)	58 (92.1)	0.98 (0.87-1.09)	

Abbreviations: ICU, intensive care unit; Pao_2/Fio_2, partial pressure of arterial oxygen/fraction of inspired oxygen.

[a] One patient in the standard care group was admitted to the ICU without a Pao_2/Fio_2 ratio less than 150 mm Hg.

Table 3. Adverse Events by System Organ Class and Treatment Arm

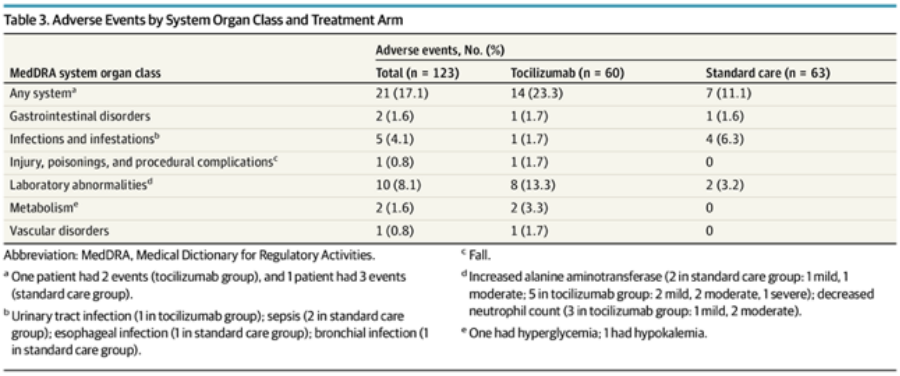


Table 3. Adverse Events by System Organ Class and Treatment Arm

MedDRA system organ class	Adverse events, No. (%)		
	Total (n = 123)	Tocilizumab (n = 60)	Standard care (n = 63)
Any system[a]	21 (17.1)	14 (23.3)	7 (11.1)
Gastrointestinal disorders	2 (1.6)	1 (1.7)	1 (1.6)
Infections and infestations[b]	5 (4.1)	1 (1.7)	4 (6.3)
Injury, poisonings, and procedural complications[c]	1 (0.8)	1 (1.7)	0
Laboratory abnormalities[d]	10 (8.1)	8 (13.3)	2 (3.2)
Metabolism[e]	2 (1.6)	2 (3.3)	0
Vascular disorders	1 (0.8)	1 (1.7)	0

Abbreviation: MedDRA, Medical Dictionary for Regulatory Activities.

[a] One patient had 2 events (tocilizumab group), and 1 patient had 3 events (standard care group).

[b] Urinary tract infection (1 in tocilizumab group); sepsis (2 in standard care group); esophageal infection (1 in standard care group); bronchial infection (1 in standard care group).

[c] Fall.

[d] Increased alanine aminotransferase (2 in standard care group: 1 mild, 1 moderate; 5 in tocilizumab group: 2 mild, 2 moderate, 1 severe); decreased neutrophil count (3 in tocilizumab group: 1 mild, 2 moderate).

[e] One had hyperglycemia; 1 had hypokalemia.

TIME TO REASSESS TOCILIZUMAB'S ROLE IN COVID-19 PNEUMONIA

Parr JB.. JAMA Intern Med. 2020 Oct 20. doi: 10.1001/jamainternmed.2020.6557. Online ahead of print.
Level of Evidence: Other - Review / Literature Review

BLUF

In this review, a physician from the Division of Infectious Diseases at University of North Carolina at Chapel Hill examined studies on tocilizumab as a treatment for COVID-19 (Table). He found two RCTs met predefined efficacy thresholds via reduction of mechanical ventilation or death (EMPACTA, 28 day threshold; CORIMUNO-19, 14 day threshold). The author suggested observational studies have demonstrated a mortality benefit but current RCT data do not adequately support efficacy of tocilizumab in COVID-19 treatment, recommending against routine use pending more robust RCT data.

Table. Comparison of Major Tocilizumab COVID-19 Studies Reported to Date

Study characteristic	Gupta et al[3] (STOP-COVID)	Salvarani et al[1] (RCT-TCZ-COVID-19)	Hermine et al[2] (CORIMUNO-TOCI-1)	COVACTA[12]	EMPACTA[13]
Design					
Type	Observational retrospective	Randomized prospective	Randomized prospective	Randomized prospective	Randomized prospective
Blinded	NA	No	No	Yes (double)	Yes (double)
Placebo-controlled	NA	No	No	Yes	Yes
Enrollment					
No. of sites	68	24	9	67	69
Countries	US	Italy	France	Canada, Denmark, France, Germany, Italy, the Netherlands, Spain, United Kingdom, US	Brazil, Kenya, Mexico, Peru, South Africa, US
No. of participants	3924	126	131	450	389
No. tocilizumab treated	433	60[a]	63	225[b]	194[b]
Clinical severity[c]					
Moderate	No	No	No	No	No
Severe	Yes	Yes	Yes	Yes	Yes
Critical	Yes	No	No	Yes	No
Intervention					
Tocilizumab	Within 2 d of ICU admission	8 mg/kg ×2 Doses, 12 h apart	8 mg/kg ×1, Possible second dose on day 3	8 mg/kg ×1, Possible second dose	8 mg/kg ×1, Possible second dose
Comparator	Usual care	Usual care	Usual care	Usual care plus placebo	Usual care plus placebo
Outcomes[d]					
Primary, effect size	Time to death: Threshold for efficacy met; HR, 0.71 (95% CI, 0.56 to 0.92) 30-d mortality: Threshold for efficacy met; RD, 9.6% (95% CI, 3.1% to 16.0%)	Pao_2:Fio_2 <150 mm Hg, ICU admission, or death: Threshold for efficacy not met; RR, 1.05 (95% CI, 0.59 to 1.86)[e]	WHO-CPS score >5 on day 4: Threshold for efficacy not met; ARD, −9.0% (90% CrI, −21.0% to 3.1%); posterior probability of ARD <0 of 89.0% Survival without NIV or MV by day 14: Threshold for efficacy met; HR, 0.58 (90% CrI, 0.33 to 1.00), posterior probability of HR<1 of 95.0%	Difference in clinical status using a 7-category scale at day 28: Threshold for efficacy not met; OR, 1.19 (95% CI, 0.81 to 1.76)	Death or MV by day 28: Threshold for efficacy met; HR, 0.56 (95% CI, 0.32 to 0.97)
28- or 30-d mortality, tocilizumab vs comparator, effect size[f]	27.5% vs 37.1%; RD, 9.6% (95% CI, 3.1% to 16.0%)	3.3% vs 1.6%; RR, 2.10 (95% CI, 0.20 to 22.6)	11.1% vs 11.9%; aHR, 0.92 (95% CI, 0.33 to 2.53)	19.7% vs 19.4%; ARD, 0.3% (95% CI, −7.6% to 8.2%)	10.4% vs 8.6%; ARD, 2.0% (95% CI, −5.2% to 7.8%)
Trial registration	NCT04343898	NCT04346355	NCT04331808	NCT04320615	NCT04372186

Abbreviations: aHR, adjusted hazard ratio (HR); ARD, median absolute risk difference; CORIMUNO-TOCI-1, Cohort Multiple Randomized Controlled Trials Open-label of Immune Modulatory Drugs and Other Treatments in COVID-19 Patients-Tocilizumab Trial; CrI, credible interval; ICU, intensive care unit; MV, mechanical ventilation; NA, not applicable; NIV, noninvasive ventilation; OR, odds ratio; RCT-TCZ-COVID-19, Open-label Randomized Multicenter Study to Evaluate the Efficacy of Early Administration of Tocilizumab in Patients With COVID-19 (coronavirus disease 2019) Pneumonia; Pao_2:Fio_2, ratio of the partial pressure of arterial oxygen to the fraction of inspired oxygen; RD, risk difference; RR, rate ratio; STOP-COVID, Study of the Treatment and Outcomes in Critically Ill Patients With COVID-19; WHO-CPS, WHO 10-point Clinical Progression Scale.

[a] Treatment assignment at enrollment. Crossover between treatment arms was permitted in the setting of clinical worsening.

[b] Numbers are derived from ClinicalTrials.gov and F Hoffman-La Roche Ltd.[12,13] Number of tocilizumab-treated participants is assumed based on planned 1:1 tocilizumab to placebo assignment.

[c] Definitions varied by study. This classification attempts to group by National Institutes of Health COVID-19 management categories.[7] Patients were or were not included with a given NIH severity scale.

[d] Efficacy estimated by the STOP-COVID investigators using an emulated target trial with observational data.

[e] Stopped early by the data and safety monitoring board for futility.

[f] Not a primary outcome for all studies; included here to facilitate comparison.

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