

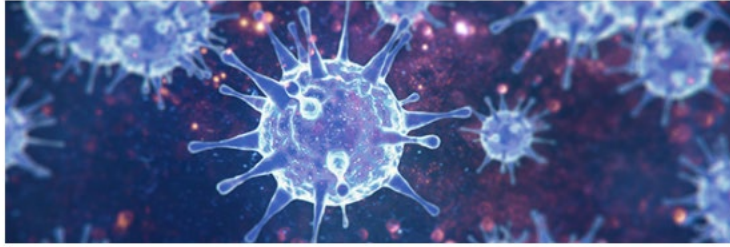


COVID-19 and Beyond

ACC and Clinical Research

John S. Rumsfeld, MD PhD FACC

Chief Science Officer & Chief Innovation Officer, American College of Cardiology
Professor of Medicine, University of Colorado School of Medicine



ACC's COVID-19 Hub

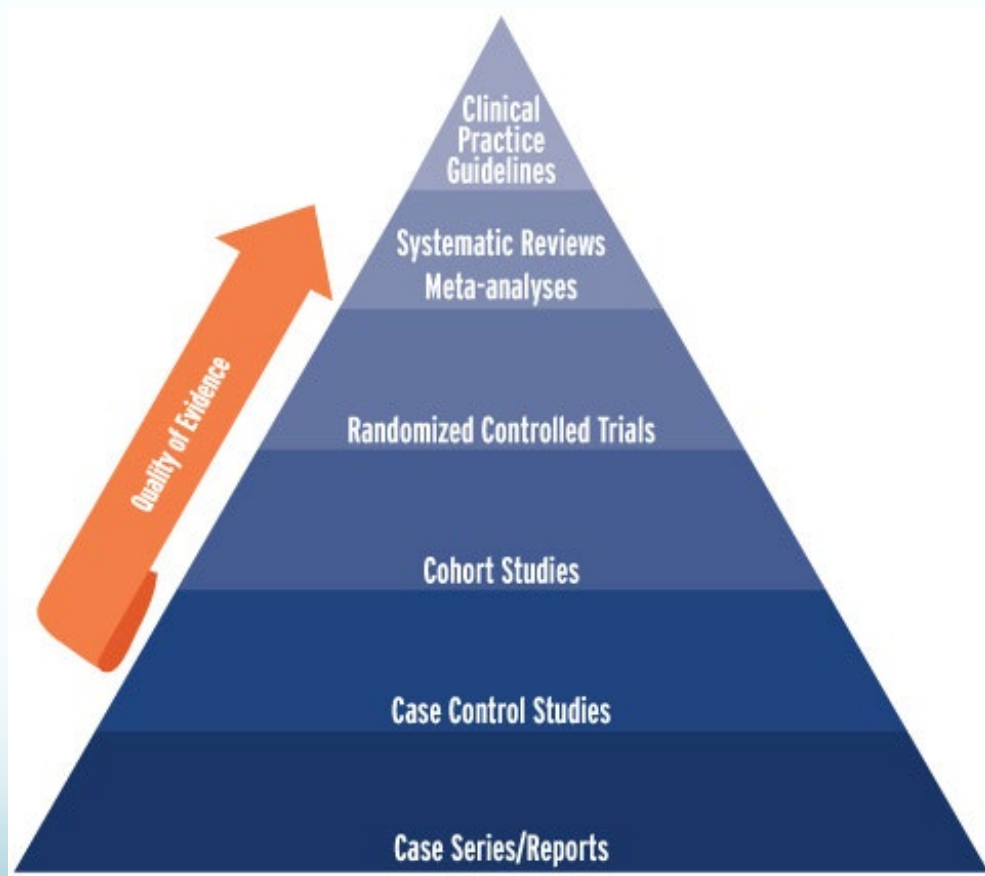
Comprehensive compilation of ACC content related to Coronavirus Disease 2019 (COVID-19)

2020

March

April

May





RAAS
Myocardial damage
HQC / Long QT
PPE
Proning teams

2020

March

JAMA Cardiology | **Original Investigation**

Association of Cardiac Injury With Mortality in Hospitalized Patients With COVID-19 in Wuhan, China

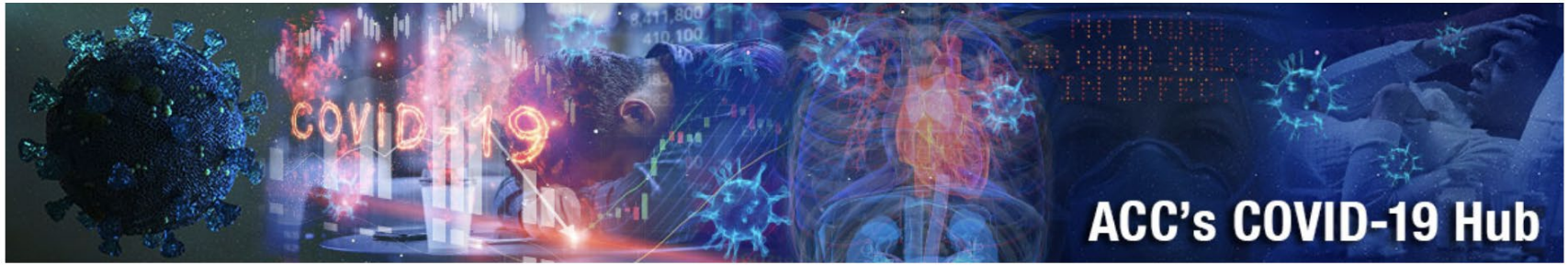
Shaobo Shi, MD; Mu Qin, MD; Bo Shen, MD; Yuli Cai, MD; Tao Liu, MD; Fan Yang, MD; Wei Gong, MMSC; Xu Liu, MD, PhD; Jinjun Liang, MD, PhD; Qinyan Zhao, MD, PhD; He Huang, MD, PhD; Bo Yang, MD, PhD; Congxin Huang, MD, PhD

JACC STATE-OF-THE-ART REVIEW

Cardiovascular Considerations for Patients, Health Care Workers, and Health Systems During the COVID-19 Pandemic



Elissa Driggin, MD,^{1,4*} Mahesh V. Madhavan, MD,^{3,5,6*} Behnood Bickdeli, MD, MS,^{3,5,6*} Taylor Chuich, PharmD,³ Justin Laracy, MD,³ Giuseppe Biondi-Zoccal, MD, MS^{STAT},^{4,7} Tyler S. Brown, MD,¹ Caroline Der Nigoghossian, PharmD,⁸ David A. Zidar, MD, PhD,⁸ Jennifer Haythe, MD,³ Daniel Brodie, MD,⁷ Joshua A. Beckman, MD,⁹ Ajay J. Kirtane, MD, SM,^{3,5,6} Gregg W. Stone, MD,^{3,4} Harlan M. Krumholz, MD SM,^{3,5,6} Sahil A. Parikh, MD^{3,5}



Thrombosis

Kawasaki-like syndrome

CV Care in COVID era

Delays in / avoidance of CV care

COVID-19 treatments / RCTs

Re-opening



April

May



ACC, SCAI, ACEP Release Consensus Statement on Management of AMI Patients During COVID-19

Apr 20, 2020

ACC News Story

COVID-19 and Thrombotic or Thromboembolic Disease: Implications for Prevention, Antithrombotic Therapy, and Follow-up

Running Head: COVID-19 and Thrombotic Disease

Journal of the American College of Cardiology

May 2020

DOI: 10.1016/j.jacc.2020.04.063

 PDF Article

ACC CLINICAL GUIDANCE

Just Accepted

Safe Reintroduction of Cardiovascular Services during the COVID-19 Pandemic: Guidance from North American Society Leadership

David A. Wood, Ehtisham Mahmud, Vinod H. Thourani, Janarthanan Sathananthan, Alice Virani, Athena Poppas, Robert

Is Remdesivir a Potential COVID-19 Treatment?

May 05, 2020

ACC News Story

Share via:       Save to Library  Print


Font Size A A A

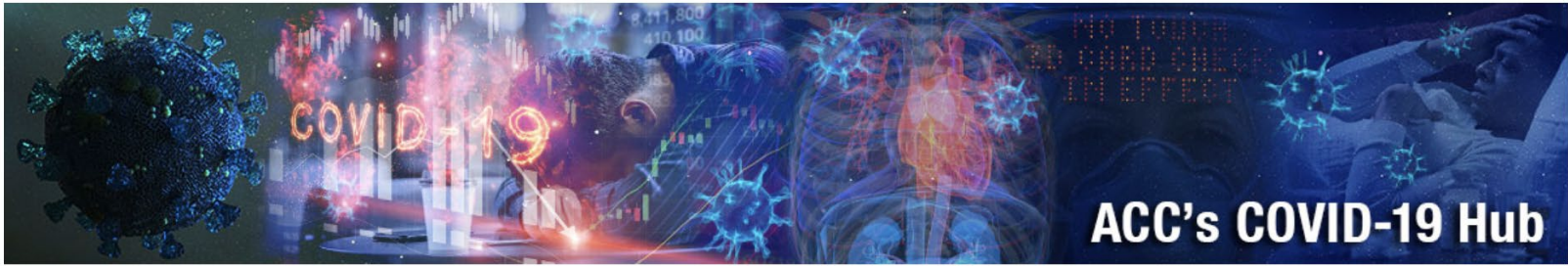
While there is limited information about the safety and effectiveness of using the investigational antiviral drug remdesivir to treat people with COVID-19, the U.S. Food and Drug Administration on May 1 issued an emergency use authorization for remdesivir in the treatment of hospitalized adults and children with severe cases of the disease.

The emergency use authorization allows for remdesivir to be distributed in the



Hydroxychloroquine
Sulphate Tablets
IP 200 mg





Ventricular Arrhythmia Risk Due to Hydroxychloroquine-Azithromycin Treatment For COVID-19

Mar 29, 2020

Cardiology Magazine

>150 trials launched

2020

March

April

May

Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis



THE LANCET

Mandeep R Mehra, Sapan S Desai, Frank Ruschitzka, Amit N Patel

www.thelancet.com Published online May 22, 2020

Summary

Background Hydroxychloroquine or chloroquine, often in combination with a second-generation macrolide, are being widely used for treatment of COVID-19, despite no conclusive evidence of their benefit. Although generally safe when used for approved indications such as autoimmune disease or malaria, the safety and benefit of these treatment regimens are poorly evaluated in COVID-19.

Methods We did a multinational registry analysis of the use of hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19. The registry comprised data from 671 hospitals in six continents. We included patients hospitalised between Dec 20, 2019, and April 14, 2020, with a positive laboratory finding for SARS-CoV-2. Patients who received one of the treatments of interest within 48 h of diagnosis were included in one of four treatment groups (chloroquine alone, chloroquine with a macrolide, hydroxychloroquine alone, or hydroxychloroquine with a macrolide), and patients who received none of these treatments formed the control group. Patients for whom one of the treatments of interest was initiated more than 48 h after diagnosis or while they were on mechanical ventilation, as well as patients who received remdesivir, were excluded. The main outcomes of interest were in-hospital mortality and the occurrence of de-novo ventricular arrhythmias (non-sustained or sustained ventricular tachycardia or ventricular fibrillation).

Findings 96032 patients (mean age 53·8 years, 46·3% women) with COVID-19 were hospitalised during the study period and met the inclusion criteria. Of these, 14888 patients were in the treatment groups (1868 received chloroquine, 3783 received chloroquine with a macrolide, 3016 received hydroxychloroquine, and 6221 received hydroxychloroquine with a macrolide) and 81144 patients were in the control group. 10698 (11·1%) patients died in hospital. After controlling for multiple confounding factors (age, sex, race or ethnicity, body-mass index, underlying cardiovascular disease and its risk factors, diabetes, underlying lung disease, smoking, immunosuppressed condition, and baseline disease severity), when compared with mortality in the control group (9·3%), hydroxychloroquine (18·0%; hazard ratio 1·335, 95% CI 1·223–1·457), hydroxychloroquine with a macrolide (23·8%; 1·447, 1·368–1·531), chloroquine (16·4%; 1·365, 1·218–1·531), and chloroquine with a macrolide (22·2%; 1·368, 1·273–1·469) were each independently associated with an increased risk of in-hospital mortality. Compared with the control group (0·3%), hydroxychloroquine (6·1%; 2·369, 1·935–2·900), hydroxychloroquine with a macrolide (8·1%; 5·106, 4·106–5·983), chloroquine (4·3%; 3·561, 2·760–4·596), and chloroquine with a macrolide (6·5%; 4·011, 3·344–4·812) were independently associated with an increased risk of de-novo ventricular arrhythmia during hospitalisation.

Interpretation We were unable to confirm a benefit of hydroxychloroquine or chloroquine, when used alone or with a macrolide, on in-hospital outcomes for COVID-19. Each of these drug regimens was associated with decreased in-hospital survival and an increased frequency of ventricular arrhythmias when used for treatment of COVID-19.

multinational registry
671 hospitals; 6 continents
96,032 COVID-19 patients

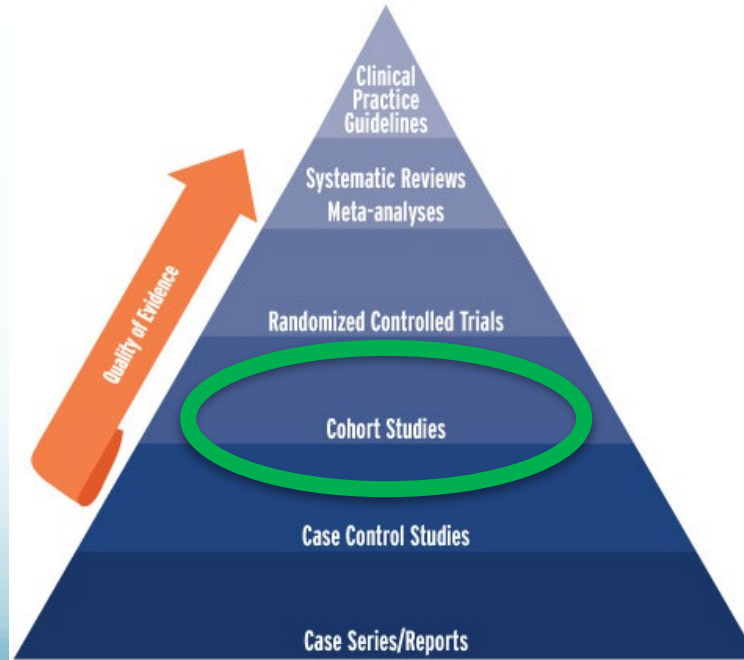
↑ risk of mortality
risk of ventricular arrhythmias

Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis



Mandeep R Mehra, Sapan S Desai, Frank Ruschitzka, Amit N Patel

THE LANCET



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THE LANCET

THE CORONAVIRUS CRISIS

WHO Halts Hydroxychloroquine Trial Over Safety Concerns

May 25, 2020 · 4:34 PM ET

Nigeria goes on with hydroxychloroquine clinical trials

We believe in hydroxychloroquine, says director of Nigeria's National Agency for Food and Drug Administration and Control

Felix Tih | 27.05.2020

24th May 2020

To all RECOVERY Principal Investigators

Recruitment to the RECOVERY trial (including the Hydroxychloroquine arm) REMAINS OPEN

Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis



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Mandeep R Mehra, Sapan S Desai, Frank Ruschitzka, Amit N Patel

← Thread



Robert M Califf @califf001 · May 24

Important statement from RECOVERY Trial in UK about continuing RCT of hydroxychloroquine. @texhern @HeartBobH @gcfmd @PCORnetwork @ASlavitt recoverytrial.net/files/professi.

💬 14

↻ 97

❤️ 234



Robert M Califf @califf001 · May 24

But, frankly i'm disturbed by the number of highly health literate people (including some regulators) who look at observational studies and pronounce that the evidence is already in. Importantly, the ongoing RCTs have independent data monitoring committees.



Robert M Califf @califf001 · May 24

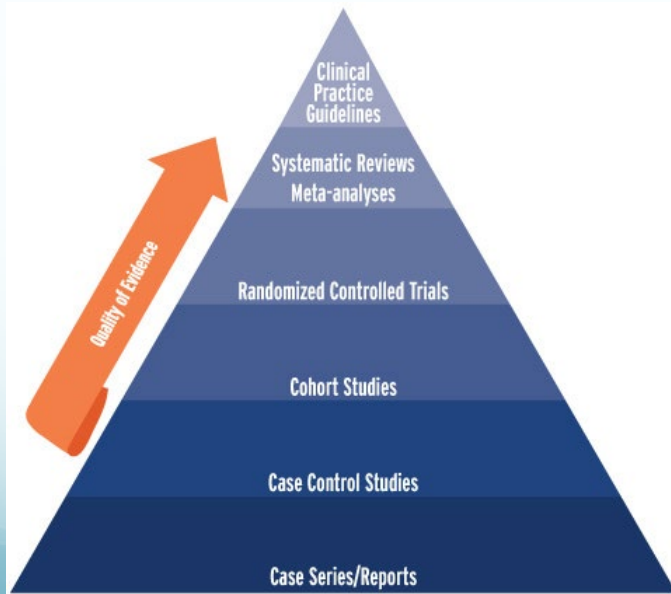
And best have all concluded: RCTs are needed. So, let's get a definitive answer from RCTs asap rather than jumping to conclusions one way or another. Random assignment is a gift for which we should be grateful as we seek truth.

💬 4

↻ 7

❤️ 61





Has COVID-19 changed the way you think about clinical evidence?

What are the largest challenges and opportunities for clinical research?

What are the key questions we should be addressing?

How can ACC lead?