

The Vital Role of Whistleblower Scientists in Exposing Fraudulent Research During the Pandemic

Mary Inman, Esq.
Elisabeth Bik, PhD

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Pandemic presents perfect conditions for Research fraud

- Government has poured Billions of \$\$ into research grants to develop, manufacture & distribute COVID therapeutics (e.g. Operation Warp Speed for vaccines)
- Although DOJ has prioritized fighting COVID frauds, insufficient resources to oversee all the spending -- limited oversight

2

Cue the Whistleblower Watchdogs

- Surge in # of whistleblower reports during the pandemic (e.g., SEC tips increase 35%)
- Prototypical Whistleblower Insiders
 - Rebekah Jones: data scientist @ Florida Dept. Public Health, exposes DPH's manipulation of COVID data for political purposes
- Whistleblower Outsiders too
 - Science sleuths like Dr. Elisabeth Bik who use their expertise to review research & uncover fraud

3

False Claims Act: Rewards & Protects Research Whistleblowers

- WBs with info re: fraud in government-funded research projects are empowered to file qui tam lawsuit in government's name & receive % of gov't recovery as reward
- False Claims Act has anti-retaliation provision protecting whistleblowers from retaliation for speaking up

4

Types of Successful False Claims Act cases by Research Whistleblowers

- Falsified grant applications, progress reports or results.
 - Duke University paid DOJ \$112M in qui tam case alleging Duke submitted to NIH & EPA grant applications & progress reports containing falsified research.
- Overcharging for time, costs and other grant-related expenses.
- Misuse of grant funds for unrelated or personal matters.
 - The Scripps Research Institute paid \$10M in qui tam case alleging TSRI improperly charged NIH-funded grants for time spent on unrelated matters.
- Undisclosed or improper conflicts of interest (e.g., undisclosed grants from foreign governments).

5

Proposed Legislative Fix: Scientific Integrity Act of 2021

- Representative Paul Tonko introduced the Act on Feb. 4, 2021.
- Per the Union of Concerned Scientists, the **Act** “would protect federal science from political interference and make sure that the public can hear directly from scientists about the work they do. It will help us make sure that the decisions made by our leaders will be based on the best available evidence not the whims of ideologues or powerful lobby groups.”

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Disclosures Elisabeth Bik

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'External' whistleblowers in science

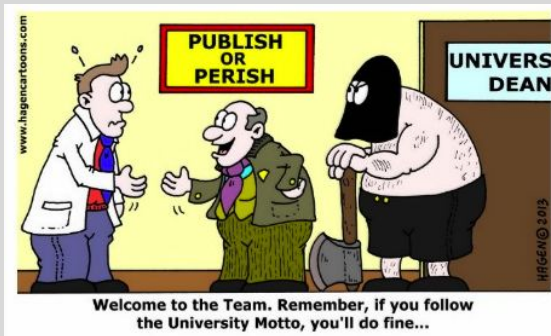
The collage features several social media profiles and articles:

- Leonid Schneider** (@schneiderleonid): Cell biologist, now certified Troll with science/medicine/environ/HigherEd/tur/forbetterscience.com/support-my-... Frankfurt on the Main, Germany. Born November 30, 1977. 1,501 Following, 10.6K Followers.
- Smut Clyde, X-Ray Haruspex** (@SmutClyde): Hyperbolic Tangent Distributed Observer. Joined April 2017. 29 Following, 1,302 Followers.
- WiseWoman** (@WeWuWiWo): I came. I saw. I played. And I block a (she/her). Location, Location, Location. 204 Following, 546 Followers.
- PS Brookes** (@PSBROOKES): Scientist, Dad, Mitochondriac, Cyclist, #WearAMask #864511320. Rochester, NY. pslab.org. 935 Following, 1,037 Followers.
- Kaoru Sakabe** (@KaoruSakabe): Former image sleuth @ASBMB @jblochem. Joined September 2016. 219 Following, 164 Followers.
- PubPeer** (@PubPeer): The online Journal Club. PubPeer.com for open evaluation of best science. 212 Following, 23.8K Followers.
- 虎仔** (@TigerBB8): Joined October 2014. 69 Following, 338 Followers.
- Cheshire** (@Thatsregrettabl): desperate stupid frustrated coward. CheshireGrins AT protonmail.com (to anonymously request I look at... Not a scientist. Joined January 2019. 364 Following, 674 Followers.
- Morty** (@mortenoxe): Senior research scientist, now s... Deep in a untrustworthy pap... 271 Following, 472 Followers.
- Dorothy Bishop** (@deevybee): Professor of developmental neurop... Main focus #devlangdis, see: you... Oxford. psy.ox.ac.uk/research. 619 Following, 38.1K Followers.
- James Heathers** (@jamesheathers): CSO @cipherskin. Biosignals, wearat... #justsaysimnice guy. The #450mov... The warm embrace of Uncle Sam... Joined September 2011. 621 Following, 15.5K Followers.
- Nick Brown** (@steam1raen): Self-appointed data police cadet, 'psychologist'. Getting older sucks... Palma de Mallorca, Spain. Joined July 2009. 166 Following, 6,562 Followers.
- Retraction Watch** (@RetractionWatch): Tracking retractions as a window... espuri.com/BNR/In Database ret... team@retractionwatch.com. New York. retractionwatch. 12 Following, 55.7K Followers.
- Clare Francis (science critic)**: From Wikipedia, the free encyclopedia. This article is about the critic of scientific publications. Clare Francis is a pseudonym used since 2010 by the author to suspected cases of plagiarism and fabricated or duplicate work in biomedical circles for his or her "uncanny knack Francis refers to himself as an "attentive reader"; their real name is unknown.
- FEBS Letters**: The Scientist's Forum. Free Access. Digital magic, or the dark arts of the 21st century—how can journals and peer reviewers detect manuscripts and publications from paper mills? Jennifer A. Byrne, Jana Christopher. First published: 17 February 2020 | <https://doi.org/10.1002/1873-3468.13747> | Citations: 3
- Max Prosser** (@maxprosser): Sapiens è un'aspirazione. Ora felicemente in pensione, l'oca - s.k.a. Sylvie Coyaud - era cronista.

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Why do scientists cheat?

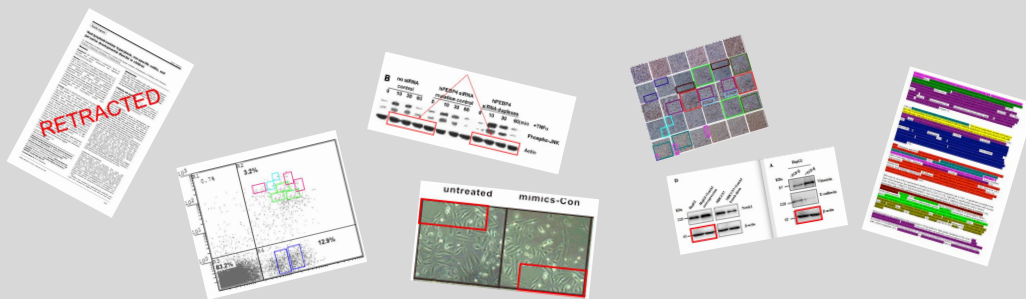
- Scientists need to publish
- Positive findings are more attractive than negative results
- Built on trust: Most scientists are honest and hard-working
- Science is not immune to fraud
- Science misconduct: plagiarism, falsification, fabrication



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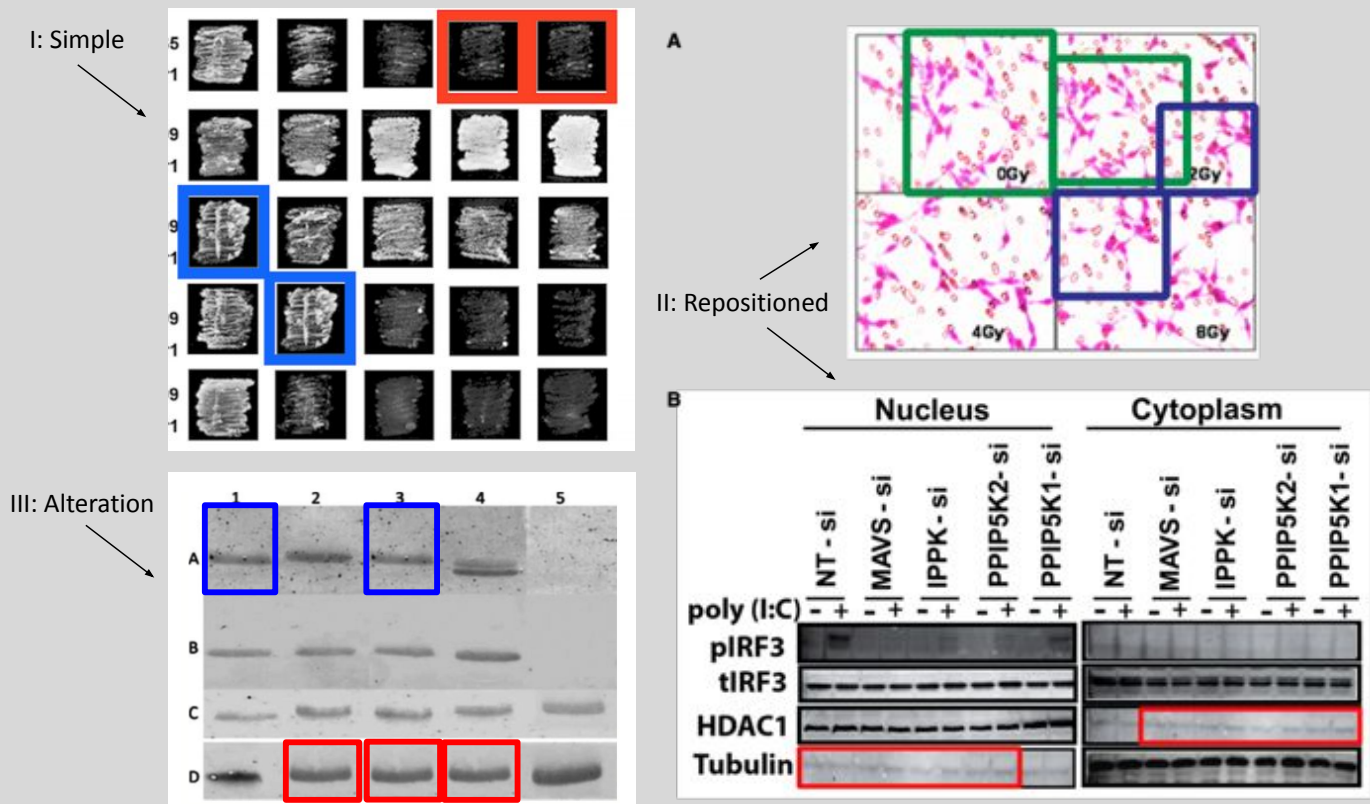
Concerns about scientific papers

- Study set-up problems (e.g. control vs treatment group)
- Misinterpretation of results
- Errors in statistics, calculations
- Unexpectedly small error bars
- Undisclosed conflicts of interest (patents, company stock)
- Animal or human subject ethics (approval, lack of consent)
- Excessive self-citations
- Plagiarism
- Peer review concerns
- **Duplicated or altered photographic figures**



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Inappropriate image duplication



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Inappropriate image duplication



The Prevalence of Inappropriate Image Duplication in Biomedical Research Publications

Elisabeth M. Bik,^a Arturo Casadevall,^{b,c} Ferric C. Fang^d


Department of Medicine, Division of Infectious Diseases, Stanford School of Medicine, Stanford, California, USA^a; Department of Molecular Microbiology and Immunology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA^b; Department of Medicine, Johns Hopkins School of Medicine, Baltimore, Maryland, USA^c; Departments of Laboratory Medicine and Microbiology, University of Washington School of Medicine, Seattle, Washington, USA^d

- 20,621 papers from 1995-2014 - by eye
- 40 journals from 14 publishers
- ~ 800 papers with duplicated figures (4%)
- 3 types: **Simple** - **Repositioned** - **Altered**
- Not all are misconduct! About half intentional: 2%
- Alteration in other data types much harder to detect

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COVID-19 papers: Fast & Furious

- Enormous amounts of COVID-19 preprints/papers
- Many opinion/editorial pieces
- Hastily written and peer-reviewed
- Retractions (n=110)
- Erodes trust of public in science



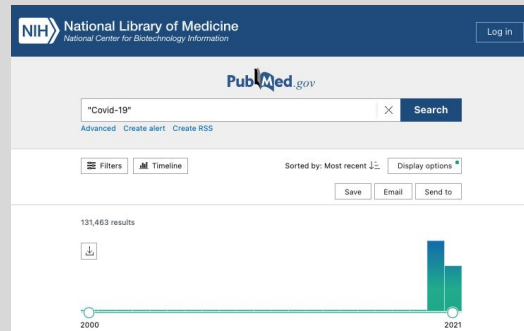
medRxiv
THE PREPRINT SERVER FOR HEALTH SCIENCES

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medRxiv is receiving many new papers on coronavirus SARS-CoV-2. A reminder: these are preliminary reports that have not been peer-reviewed. They should not be regarded as conclusive, guide clinical practice/health-related behavior, or be reported in news media as established information.

COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

16,278 Articles (12,557 medRxiv, 3,721 bioRxiv)



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National Center for Biotechnology Information

PubMed.gov


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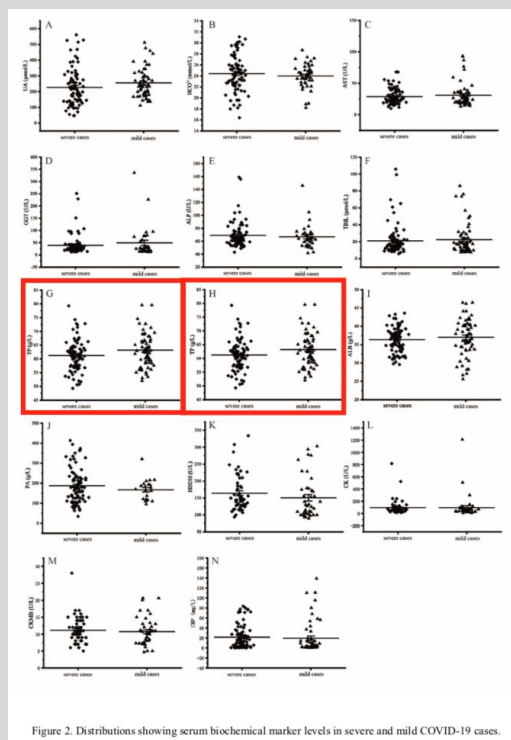
131,463 results



2000 2021

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Duplicated panels in medRxiv preprint



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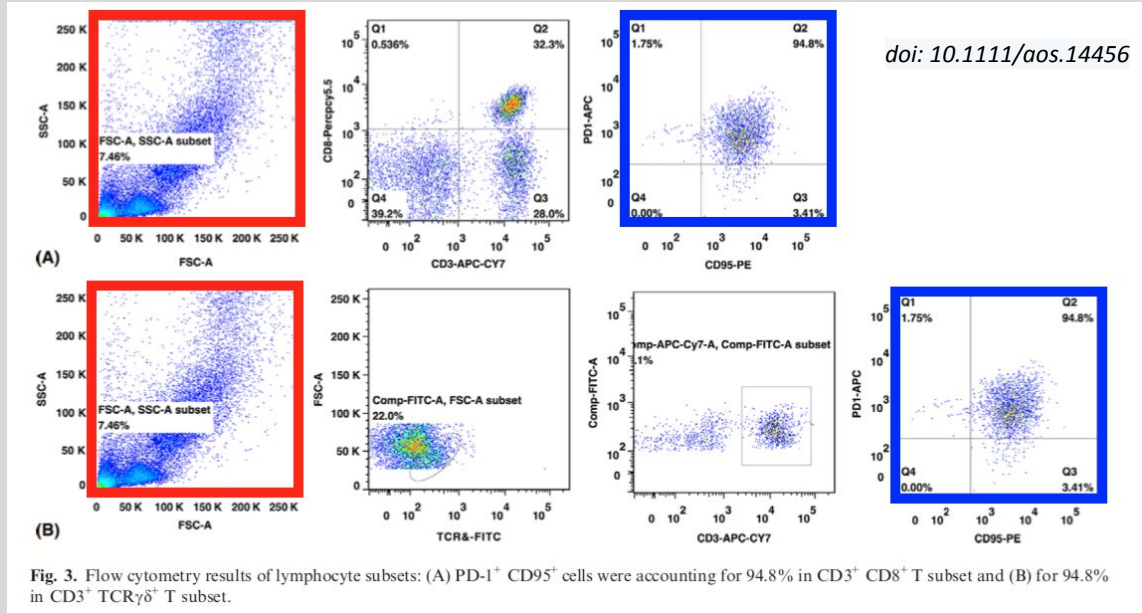
Potential biochemical markers to identify severe cases among COVID-19 patients

Comments (3)

- Preprint posted on March 23, 2020
- PubPeer comment posted on March 25, 2020
- Authors never replied, no correction
- Paper was never published

14

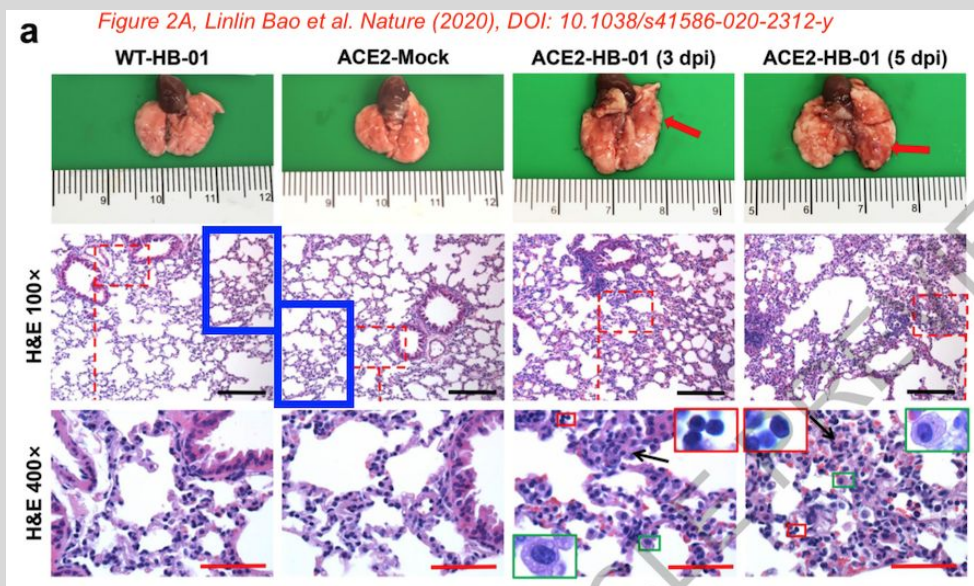
Duplicated panels in published paper



- Paper published on 14 May 2020
- PubPeer comment posted on 15 May 2020
- Authors never replied, no correction

15

Overlapping photos in a Nature paper



- Paper published on 7 May 2020
- PubPeer comment posted on 11 May 2020
- Figure silently corrected sometime after that

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Hydroxychloroquine: A game changer?

International Journal of Antimicrobial Agents
Available online 20 March 2020, 105949
In Press, Journal Pre-proof

Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial

Philippe Gautret ^{a, b, 5}, Jean-Christophe Lagier ^{a, c, 5}, Philippe Parola ^{a, b}, Van Thuan Hoang ^{a, b, d}, Line Meddeb ^a, Morgane Mailhe ^a, Barbara Doudier ^a, Johan Courjon ^{e, f, 6}, Valérie Giordanengo ^h, Vera Esteves Vieira ^a, Hervé Tissot Dupont ^{a, c}, Stéphane Honoré ^{i, j}, Philippe Colson ^{a, c}, Eric Chabrière ^{a, c}, Bernard La Scola ^{a, c}, Jean-Marc Rolain ^{a, c}, Philippe Brouqui ^{a, c}, Didier Raoult ^{a, c, 6, 7}

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Received 16 March 2020, Accepted 17 March 2020, Available online 20 March 2020.

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<https://doi.org/10.1016/j.ijantimicag.2020.105949>

Donald J. Trump
@realDonaldTrump

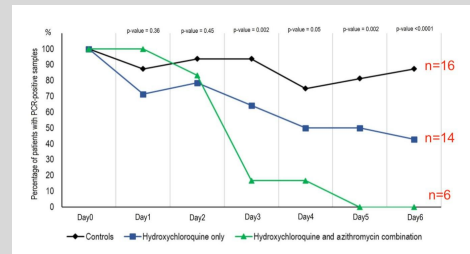
HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine. The FDA has moved mountains - Thank You! Hopefully they will BOTH (H works better with A, International Journal of Antimicrobial Agents).....

7:13 AM · Mar 21, 2020 · Twitter for iPhone

103.3K Retweets 386.8K Likes



Didier Raoult has complained about the "dictatorship of the methodologists" who insist on randomization and control groups in clinical trials. <https://www.nature.com/articles/d41586-020-00116-1> Science, 9 April 2020



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A critical review

- Ethical issues: study may have started before ethical approval
- Differences between control and treatment groups
 - Age - Hospital - Different PCR tests - Not randomized
- Six treated patients left out of study (1 died, 3 went to ICU)
- Peer review in 24h
- Editor in Chief of journal is an author

Science Integrity Digest
A blog about science integrity, by Elisabeth Bik, for Harbers-Bik LLC. Support my work at [Patreon.com/elisabethbik](https://patreon.com/elisabethbik)

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Thoughts on the Gautret et al. paper about Hydroxychloroquine and Azithromycin treatment of COVID-19 infections

There has been a lot of excitement – and even a presidential tweet about a recent paper from the lab of Didier Raoult, an infectious disease specialist in Marseille, France. But although this study might offer a glimmer of hope, there are some serious problems with the paper too.

The paper, by Gautret et al., first appeared on 16 March 2020 as a [preprint on medRxiv](#). A “preprint” is a raw version of a scientific paper that has

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Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial

Philippe GAUTRET, Jean-Christophe LAGIER, Philippe PAROLA, Van Thuan HOANG, Line MEDDEB, Morgane MAILHE, Barbara DOUDIER, Johan COURJON, Valérie GIORDANENGO, Vera ESTEVES VIEIRA, Hervé TISSOT DUPONT, Stéphane HONORÉ, Philippe COLSON, Eric CHABRIÈRE, Bernard LA SCOLA, Jean Marc ROLAIN, Philippe BROUQUI, Didier RAOULT

bioRxiv (2020)

0 comments

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Hydroxychloroquine: does it not work?

- Lancet / NEJM papers, now both retracted
- 96,000 COVID-19 patients from 671 hospitals
- Data provided by Surgisphere
- Surgisphere founder: photos of concern in 2005 PhD paper

Articles

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

Monday 4 May, 10:01 AM, Front Row Health, And AP/ML

Summary
Background Hydroxychloroquine or chloroquine, when in combination with a second-generation cephalosporin, are widely used for treatment of COVID-19, despite no conclusive evidence of their benefit. Although hydroxychloroquine is used for a spectrum of infectious such as autoimmune disease or malaria, the safety and efficacy of these 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 42 countries. Patients who received one of the treatments of interest within 48 h of diagnosis were included in the four treatment groups (hydroxychloroquine with a macrolide, hydroxychloroquine without a macrolide, chloroquine with a macrolide, and chloroquine without a macrolide), and patients who received none of these treatments formed the control group. Patients for whom use of the treatments of interest was initiated more than 48 h after diagnosis, or who had other medical conditions, as well as patients who received immunosuppressants, were excluded. The main outcome was in-hospital mortality and the occurrence of adverse ventricular arrhythmias (QTc interval >450 ms, torsades de pointes, or ventricular fibrillation).

Findings 96 022 patients (mean age 53.8 years, 66.3% men) were included in the analysis. 47 015 were hospitalised during the study period and met the inclusion criteria. Of these, 23 507 were in the treatment group (48% received hydroxychloroquine with a macrolide, 23% received hydroxychloroquine, and 42% received hydroxychloroquine with a macrolide) and 23 509 in the control group. 19 618 (21%) patients died in hospital. After controlling for multiple comparisons, we found no differences in in-hospital mortality, 30-day mortality, or 90-day mortality between the treatment and control groups. In-hospital mortality (OR 0.96, 95% CI 0.92–1.00), 30-day mortality (OR 1.00, 95% CI 0.96–1.04), and 90-day mortality (OR 1.00, 95% CI 0.96–1.04) were independently associated with the treatment. In-hospital mortality, compared with the control group (0.9%), hydroxychloroquine with a macrolide (0.9%), hydroxychloroquine with a macrolide (0.9%), chloroquine with a macrolide (0.9%), and chloroquine with a macrolide (0.9%) were independently associated.

Interpretation The combination of hydroxychloroquine or chloroquine, when used alone or with a macrolide, does not improve the clinical response of outpatients with COVID-19. Each of these drug regimens was associated with decreased in-hospital mortality and improved response of outpatients with COVID-19.

Funding Wellcome Distinguished Chair in Advanced Cardiovascular Medicine at Brigham Women's Hospital.

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Introduction
The absence of an effective treatment against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) COVID-19 to limit its spread as a small number of antiviral agents have been shown to have variable responses in treatment of COVID-19. For example, these reported therapeutic agents are the antimalarial drug chloroquine, which is used to treat autoimmune diseases such as systemic lupus erythematosus and rheumatoid arthritis.¹ These drugs have been shown in laboratory conditions to have antiviral activity against SARS-CoV-2.² However, the use of this class of drugs for infection has led clinicians to reflect upon their potential to be effective for other medical conditions in the treatment of COVID-19. For example, these reported therapeutic agents are the antimalarial drug chloroquine, which is used to treat autoimmune diseases such as systemic lupus erythematosus and rheumatoid arthritis.¹ These drugs have been shown in laboratory conditions to have antiviral activity against SARS-CoV-2.² However, the use of this class of drugs for infection has led clinicians to reflect upon their potential to be effective for other medical conditions in the treatment of COVID-19.

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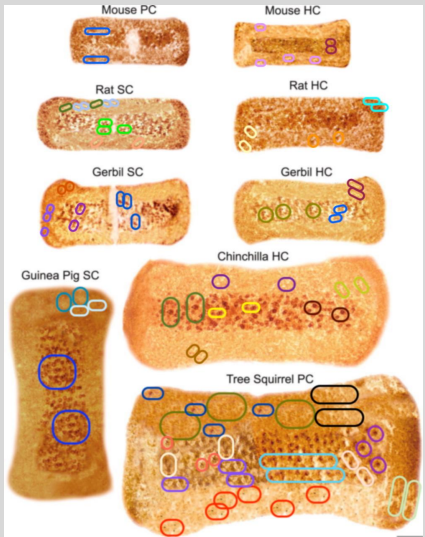
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Legal threats for science whistleblowers

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Scientists rally around misconduct consultant facing legal threat after challenging COVID-19 drug researcher

By Cathleen O'Grady | May 27, 2021, 5:05 PM

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NEWS | 27 May 2021

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World expert in scientific misconduct faces legal action for challenging integrity of hydroxychloroquine study

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Science Misconduct: Discussion

- What is the percentage of science misconduct?
- Why do people commit science misconduct?
- Conflicts of interest (*publishers, institutions*)?
- Legal protection for whistleblowers?
- Tremendous cost of science misconduct (*scientists, science*)
- @MicrobiomDigest #ImageForensics

