Outcomes of hydroxychloroquine usage in United States veterans hospitalized with Covid-19

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Abstract

BACKGROUND: Despite limited and conflicting data on the use of hydroxychloroquine in patients with Covid-19, the U.S. Food and Drug Administration has authorized the emergency use of this drug when clinical trials are unavailable or infeasible. Hydroxychloroquine, alone or in combination with azithromycin, is being widely used in Covid-19 therapy based on anecdotal and limited observational evidence. METHODS: We performed a retrospective analysis of data from patients hospitalized with confirmed SARS-CoV-2 infection in all United States Veterans Health Administration medical centers until April 11, 2020. Patients were categorized based on their exposure to hydroxychloroquine alone (HC) or with azithromycin (HC+AZ) as treatments in addition to standard supportive management for Covid-19. The two primary outcomes were death and the need for mechanical ventilation. We determined the association between treatment and the primary outcomes using competing risk hazard regression adjusting for clinical characteristics via propensity scores. Discharge and

and no HC groups were 13.3%, 6.9%, 14.1%, respectively. Compared to the no HC group, the risk of death from any cause was higher in the HC group (adjusted hazard ratio, 2.61; 95% CI, 1.10 to 6.17; P=0.03) but not in the HC+AZ group (adjusted hazard ratio, 1.14; 95% CI, 0.56 to 2.32; P=0.72). The risk of ventilation was similar in the HC group (adjusted hazard ratio, 1.43; 95% CI, 0.53 to 3.79; P=0.48) and in the HC+AZ group (adjusted hazard ratio, 0.43; 95% CI, 0.16 to 1.12; P=0.09), compared to the no HC group. CONCLUSIONS: In this study, we found no evidence that use of hydroxychloroquine, either with or without azithromycin, reduced the risk of mechanical ventilation in patients hospitalized with Covid-19. An association of increased overall mortality was identified in patients treated with hydroxychloroquine alone. These findings highlight the importance of awaiting the results of ongoing prospective, randomized, controlled studies before widespread adoption of these drugs.

Competing Interest Statement

Disclosure forms provided by the authors are available with the NEJM. JA is a co-founder of iVeena Holdings, iVeena Delivery Systems and Inflammasome Therapeutics, and has received consultancy fees from Allergan, Biogen, Boehringer Ingelheim, Immunovant, Janssen, Olix Pharmaceuticals, Retinal Solutions, and Saksin LifeSciences, all unrelated to this work. JA is named as an inventor on a patent application filed by the University of Virginia relating to Covid-19 but unrelated to this work. SSS has received research grants from Boehringer Ingelheim, Gilead Sciences, Portola Pharmaceuticals, and United Therapeutics, all unrelated to this work. The other authors declare no competing interests.

Funding Statement

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Author Declarations

All relevant ethical guidelines have been followed; any necessary IRB and/or ethics committee approvals have been obtained and details of the IRB/oversight body are included in the manuscript.

Yes

All necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived.

Yes

I understand that all clinical trials and any other prospective interventional studies must be registered with an

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Yes

I have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.

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Name

Eric Hall • 3 hours ago

But not a prospective study with a randomized control group. How do we know the HCQ groups weren't just sicker and it was used more like maximum medical therapy. Correlation doesn't equal causation.

Reply • Share ›

Jorgen Schultz • 5 hours ago

Interesting - and chocking, I must say. I hope the report I have read on medRxiv is not final, because I am missing the following:
1) As I understand it, the combo-treatment is effective in treating patients with Coronavirus BEFORE it is "to late". Giving a treatment with known side effects during late stage infection is recommended by?
2) The screening done (on patients) prior to treatment - I must have missed it or? Just to compare: as I understand it, in IHU's treatment (besides patient-groups being not comparable) screening is done prior to any medication, and patients in risk form a kind of control group as best as can be in this effort to safe lives.
3) Dosage and duration of treatment?
4) Did patients with cardiovascular symptoms receive hydroxychloroquine? Likewise with patients showing symptoms of "Cytokine Storms"?
5) According to "Cytokine storm and immunomodulatory therapy in COVID-19: role of chloroquine and anti-IL-6 monoclonal antibodies" by Ming Zhao, Hydroxychloroquine is mentioned for its effect to inhibit viral replication. Is that not very much prior to the case of the patients in this study?
Did other - and more relevant drugs - replace the use of Hydroxychloroquine if the later stages of

But here - another war seems to be fought!
With human sacrifice and casualties as a result.
Colatteral damage?

I am chocked and saddened by the loss of life during this study.

Reply • Share ›

Three-legged Crow • 6 hours ago

Where's zinc mentioned in this study?

1 Reply • Share ›

Graham Senior-Milne • 6 hours ago

'CONCLUSIONS: In this study, we found no evidence that use of hydroxychloroquine, either with or without azithromycin, reduced the risk of mechanical ventilation in patients hospitalized with Covid-19. An association of increased overall mortality was identified in patients treated with hydroxychloroquine alone.'

What's missing? Yep, mortality with HC + AZ. In the text it says:

'Compared to the no HC group, the risk of death from any cause was higher in the HC group (adjusted hazard ratio, 2.61; 95% CI, 1.10 to 6.17; P=0.03) but not in the HC+AZ group (adjusted hazard ratio, 1.14; 95% CI, 0.56 to 2.32; P=0.72).'

In other words, and unless I can't read plain English, the risk of death is reduced by HC + AZ.

Reply • Share ›

stylin19 • 8 hours ago • edited

Index dates range from March 9, 2020 to April 11, 2020, and patients were followed from index until hospital discharge or death.The period prior to index is designated as the baseline period and on or after index is designated the follow-up period.

something is not quite right about this study.

There were only 731 COVID-19 cases in the U.S. end of day 03/08/2020.

Why did the VA start using hydroxychloroquine so early ?

FDA "emergency use" edict wasn't approved until 03/29/2020.

FDA already has a "compassionate use" for drugs.
It's usually at end of life situations.

Per your study:
"However, hydroxychloroquine, with or without azithromycin, was more likely to be prescribed to patients with more severe disease, as assessed by baseline ventilatory status

You really need to provide more data regarding Hospitalization\treatment dates for each patient.

Reply • Share ›

Niall Toibin • 8 hours ago

First Point

Obviously the state of the patient and their progression may have influenced the decision to prescribe HC. To quote the paper

QUOTE
baseline characteristics corresponding to clinical severity varied across the three groups of patients and could have influenced the non-randomized utilization of hydroxychloroquine and azithromycin
UNQUOTE

This is the context in which the following has to be taken

QUOTE
A total of 368 patients were evaluated. Rates of death in the HC, HC+AZ, and no HC groups were 27.8%, 22.1%, 11.4%, respectively.
UNQUOTE

No media outlet should report the second quote without the first.

see more

Reply • Share ›

Dr Mubarak khan • 9 hours ago

I keenly read this manuscript. My views. Following are the limitations before coming to conclusions
1. This is still not a published study in any top journals and must be taken back based on following points
2. Although a good write up, it's retrospective study with hurried conclusions
3. Selection criteria is just based on hospitalised COVID19 patients. And at which stage drugs administered is not clear in all three groups
4. Outcome criteria is only either death or discharge. What happened to those who got discharged ? Whether there was any hastening in improvement due to these drugs? Whether there is shortening of duration due to drugs from COVID positive to negative?
5. Whether these drugs have been tried as prophylaxis? Or only used in hospitalised patients?
6. All patients included are with mean age at 70 and with many comorbidities
7. What dosages used for hcq and azythromicin ? How many days treatment given?
8. What type of pharmacovigilance noted for all groups?
9. Whether at anytime drugs discontinued due to side effects?
10. What side effects were obvious during the treatment period?

COVID-19 infected hospitalised patients... it will be very much premature to conclude these drug's role based on short experience and points raised above*

Reply • Share ›

Dominique Joly • 11 hours ago

Major issue: the number of days between the first symptom and the beginning of hosp/treatments is not indicated.

Reply • Share ›

Cheri Trigg • 15 hours ago

According to MedCram Zinc is what actually helps. Chloroquine is how the zinc gets into the cells. MedCram is a medical journal on Youtube. Update #32 and 34 go into depth on this. It is tragic to use a medication meant as a delivery system and not use it to deliver. Not sure to laugh or bawl. I hope the word gets out to use zinc before the zithromyacin at least.

Reply • Share ›

Bob Joy • 15 hours ago • edited

NY Doctor Treats 699 covid Cases With 100% Success , zinc included

https://everlast.mercola.co...

1 Reply • Share ›

JC • 15 hours ago

Can you provide any details about how much of the drug you gave each patient? It's quite odd that it wasn't included in this study. Especially, since it's already known in high doses it can cause problems for patients, and if too low it wouldn't make a difference.

Reply • Share ›

Mike • 16 hours ago • edited

This was certainly an interesting paper. It's done a lot of work and the findings are notable. IMHO it warrants as much attention as the pro-HCQ study via Dr. Raoult. While it is entertaining, I will add that it is not conclusive, nor without fault. A double-blind study is still required, but it is worth the read.

Observations/Questions:

1. "hydroxychloroquine, with or without azithromycin, was more likely to be prescribed to patients with more severe disease"
2. "we cannot rule out the possibility of selection bias or residual confounding"
3. demographic: 100% male, 66% black, median age ~70 (59 youngest)
4. uses PSM, which despite a common practice, could be considered controversial (https://gking.harvard.edu/f...
5. Unless I missed it, I didn't see any specifics about how the treatments were administered.

see more

14 · Reply · Share ›

Eric H ↗ Mike • 11 hours ago

Also note that the control group had significantly fewer complicating issues such as blood pressure, hypoxia, diabetes, and last but not least the control group had a significantly lower percentage of African American patients. Presumably there was an attempt to control for these factors with the PSM, but as you noted that's not the optimal method and can lead to bias. Most importantly though, the Hazard Ratio Confidence Intervals shown in Table 5... all but one contain the number 1.0 and if I understand correctly this signifies that the results are not statistically significant which blows a gigantic hole in the conclusion, which conveniently failed to mention the less than meaningful intervals. The sixth confidence interval missed the 1.0 by a mere 0.15 which doesn't help matters.

· Reply · Share ›

ᴀʏʏLMAO ↗ Mike • 14 hours ago

"5. Unless I missed it, I didn't see any specifics about how the treatments were administered."

I agree. Also no mention of zinc sulfate. HC is a zinc ionophore. The intent of the treatment is to target zinc to the lysosomes.

People have been criticizing anecdotal evidence of the positive effect HC has on patient outcomes. In this case all I see is negative anecdotal evidence.

· Reply · Share ›

honesttalk ↗ Mike • 14 hours ago

Why wasn't ZINC SULFATE administered? What were they thinking? It was observed in 2004 that ZINC interferes with viral load increases in respiratory infections. At that time the exact mechanism by which ZINC interferes was not established.

· Reply · Share ›

David B Joyce • 16 hours ago • edited

19 patient shifted fromNo HC to HC(7) or HC+AZ(12) after ventilation. Ventilation is obviously a sign of increasing severity and greater risk of death. If all of these ventilations resulted in death, then the pre ventilation treatment fatality statistics might look like 22%(HC), 13% (HC+Az) and 21% No HC. Need the data on individual outcomes. Also not impressed with the cohorts.

SPo2 >95: 63%(HC) 57.5%(HC+Az) 73.4%(No HC)
BP> 159: 19.6% 9.7% 9.5%
creatinine>5 17.5% 11.5% 7.6%

negative outcome. Lots of "missing" counts in the control group, suggesting maybe their (presumably normal) counts were likely not noteworthy.

Lymphocytes – no. (%)

<800 per mm3 24 (24.7) 34 (31.0) 22 (13.9) 0.021

800-3,000 per mm3 54 (55.7) 60 (53.1) 90 (57.0)

>3,000 per mm3 1 (1.0) 2 (1.8) 7 (4.4)

Missing 18 (18.6) 17 (15.0) 39 (24.7)

Reply • Share ›

Eric H ➚ David B Joyce • 11 hours ago

Control group also had a significantly lower percentage of Afro Americans which we know now have significantly higher mortality rates. In addition, it looks like the "diabetes with complications" was also skewed in favor of the "control" group.

Reply • Share ›

honesttalk ➚ David B Joyce • 15 hours ago

Why wasn't ZINC SULFATE included in the treatment? ZINC is what interferes with the viral load increase.

5 Reply • Share ›

stickler • 17 hours ago

Every news media seems to be including this same sentence: "The nationwide study was not a rigorous experiment," which to trump supporters means that its conclusions are completely untrustworthy and it can be summarily disregarded as a politically motivated product of the deep state. In what way did this study lack rigor? Does there appear to be anything lacking in the design, methodology, data, analysis, interpretation or reporting of results, or is it more a matter of just awaiting peer review?.

Reply • Share ›

Eric H ➚ stickler • 10 hours ago

It was not a randomized clinical trial in any sense of the word. It was a collection of anecdotes with some statistical manipulations used to try to reverse engineer some randomness into the cohort selections. It used a method called PSM for randomization and this method is no longer recommended for use as it can introduce bias. There are better ways. Zinc was never once mentioned in the study but zinc is a crucial element in the HCQ "cocktail". At the very least they should have randomized on patient zinc status. Zinc deficiency is extremely common among the elderly. Not even one doctor was interviewed to get a sense of what the decision criteria was for using or not using HCQ. This has a

showed some efficacy. A good study would have more patients and the treatment protocols need to be well defined. This study is actually much worse in that regard than the much criticized French study.

Reply • Share ›

Michael Kyba • 17 hours ago

A cursory browse through Table 2 of the paper shows that the patients that would eventually comprise the HC group were the sickest upon admission, the HC+AZ patients were intermediate and the patients that would elect no HC group were the least sick. This is prior to intervention.

This sort of sampling bias highlights the importance of double blind randomization to determine efficacy. Such an a priori correlation might be due to sicker patients opting for experimental treatments at a higher rate. In any case, it would not be wise to interpret these data as indicating that the interventions cause the worse outcomes. The underlying health state is probably responsible.

Some examples follow, then a criticism of what the authors have written into their Results and Discussion.

Known risk factors include age, weight and blood pressure; and signs of severe disease include kidney damage.

Browsing through table 2 looking for parameters with lowish p-values:
Mean systolic blood pressure differences between groups showed a p-value of just under 0.05 (statistically significant), with values of 136, 132, and 129 across the groups (HC, HC+AZ, no HC),

see more

12 Reply • Share ›

Eric H ➚ Michael Kyba • 10 hours ago

Best review I've seen so far. Thanks!. I would ask you look at Table 5 and confirm my observation that the Hazard Ratio Confidence Intervals all contain or nearly overlap the number 1.0 which I believe indicates that the results are statistically insignificant. If I am correct about this then shame on the authors for not pointing this out in the conclusion or the discussion.

Reply • Share ›

Mike Cee • 17 hours ago

This paper is flawed and should be withdrawn immediately.
1) This paper is flawed due to the limitation discussed on page 12 about the likelihood that the HCQ group, "However, hydroxychloroquine, with or without azithromycin, was more likely to be prescribed to patients with more severe disease, as assessed by baseline ventilatory status and metabolic and hematologic parameters."

thus stops the progression of the disease.
3) This study did not document the dosage given to the patients. That would have been a helpful inclusion so we could understand if the patients who died were actually poisoned by excessive the treatment.
4) HCQ prescribed in patients in the first week after SYMPTOMS ONSET to include a zinc supplement which anecdotal evidence suggests a dual function of the combination: The HCQ provides an avenue for the zinc to enter the Type 2 lung cell where it interferes with the virus replication process.

8 ^ | v • Reply • Share ›

Eric H • 18 hours ago

The Hazard Ratio confidence intervals in Table 5 of the report shows that the findings of this study are not significant. That plus the uncertainties in the Propensity Score Matching method make it even worse. I noticed the HCQ group contained a substantially higher proportion of high blood pressure and diabetic w/complications than the control group. Worst of all, they apparently did not interview even one doctor to ascertain the range of Tx criteria used.

3 ^ | v • Reply • Share ›

docmeehan • 19 hours ago • edited

I'm not sure VA database born retrospective cohort analysis that declines to reveal drug dosing protocols contributes much to the science. Let's have those drug dosing protocols.

3 ^ | v • Reply • Share ›

deutsch • 19 hours ago

The group no HCQ had azihtromycine 31% !!!!

1 ^ | v • Reply • Share ›

Eric H ↗ deutsch • 10 hours ago

Good Point! Why were those patients not excluded?

^ | v • Reply • Share ›

Marv Goosen • 20 hours ago

The problem with this study is that it is retrospective and as the authors state in their discussion, patients in worse shape may have been put in the HC group which would also account for higher mortality. Unfortunately until a prospective study with severity matched controls is done, no conclusions can be made.

3 ^ | v • Reply • Share ›

Senad Hasanagic • 20 hours ago

Totally flowed retrospective analysis because baseline Clinical characteristics are missing (not reported) in significant number of patients. So adjustments not possible.

got the combination were 50% likely to get mech vent. The only message is that combination is superior and NO HQ alone. Otherwise, this is a biased study that misses the point - sorry!

3 ^ | v • Reply • Share ›

Savio • 21 hours ago

Cytokine bath or flooding is causing co-morbidity. HCQ can apparently reduce the inflammation in response to the virus but not counter the virus itself.

Here is a review paper describing the “Mechanisms of action of hydroxychloroquine and chloroquine: implications for rheumatology”.

https://www.nature.com/arti...

“Hydroxychloroquine and chloroquine are weak bases and have a characteristic ‘deep’ volume of distribution and a half-life of around 50 days. These drugs interfere with lysosomal activity and autophagy, interact with membrane stability and alter signalling pathways and transcriptional activity, which can result in inhibition of cytokine production and modulation of certain co-stimulatory molecules.”

1 ^ | v • Reply • Share ›

Roleigh Martin • a day ago

Why was not Zinc added to the dosage, many clinical reports have been made about how critical Zinc level monitoring and Zinc supplementation is to successful use of this Rx.

4 ^ | v • Reply • Share ›

Brandon B • a day ago

Risk of ventilation was 6.9% in HQ + AZ group and 14.1% in no Tx group. That is double. It was stated that these numbers are similar in the article. Not significant?

10 ^ | v 3 • Reply • Share ›

Rick ↗ Brandon B • 17 hours ago

And HQ+AZ actually gave lower death rate, if you group the patients only based on "pre-ventilation" treatment as in table 4. Grouping patients based on "overall hospital stay", as the analysis was done to draw their main conclusion, leads to inclusion of patients who were treated with HQ+AZ in later stage presumably because they were sicker. Based on presented stats on the clinical characteristics, the patients in HQ groups were overall sicker.

3 ^ | v • Reply • Share ›

Eric H ↗ Brandon B • 18 hours ago

Saw that too. I have to wonder if this was a typographical error. It contradicts the statement of conclusions. Which is wrong? They can't both be right.

1 ^ | v • Reply • Share ›

The early studies that were claiming success with HQ were done only on very mild cases. 85% of them weren't even running a fever. A drug might help some that were barely sick to begin with get over it faster while not helping anyone with a full blown case. Even that one had three go to the ICU and one death. Since they couldn't obtain the samples they needed from cases in the ICU or dead, those people were dropped from the study altogether.

Reply • Share ›

Thomas Aquinas ➚ Diane Merriam • 6 hours ago

From the pdf:

""However, hydroxychloroquine, with or without azithromycin, was more likely to be prescribed to patients with more severe disease, as assessed by baseline ventilatory status and metabolic and hematologic parameters. Thus, as expected, increased mortality was observed in patients treated with hydroxychloroquine, both with and without azithromycin."

The standard, successful, worldwide protocol is to begin the HCQ/Zithromax/zinc therapy at the onset of breathing difficulties, not when patients have been placed on ventilators. The current mortality rate for patients on ventilators is 50-80%.

Reply • Share ›

Eric H ➚ Diane Merriam • 10 hours ago

Interesting that you say "significantly higher". If I understand the confidence intervals in the hazard ratio Table 5, most of them indicate that there is no statistical significance at all (5 out of 6 intervals include the number 1.0).

Reply • Share ›

vlodko62 ➚ Brandon B • 18 hours ago

The relative death rates for the three groups are not encouraging.

Reply • Share ›

Doctor Hawaii ➚ Brandon B • 20 hours ago

You might want to refresh your understanding of statistics. Look at the P values and the CIs in the analysis. So, not significant is correct.

Reply • Share ›

Brandon B ➚ Doctor Hawaii • 4 hours ago

Statistically non significant in this poorly done study, but significant enough to warrant further investigation.

Reply • Share ›

Brooklyn Ease ↗ Pierre Balaz • 19 hours ago

Dosing information is important in this study as the risk of hydroxychloroquine causing prolonged QTc and Tdp is higher with 600 mg than 400 mg dosages, if rhythm disturbance contributed to death.

1 ^ | v • Reply • Share ›

Eric H ↗ Pierre Balaz • 20 hours ago

What about the zinc? With a zinc deficiency (very common in elderly) the HCQ is almost worthless.

^ | v • Reply • Share ›

Udub • a day ago • edited

Quite strange study !!! What was the purpose ? .. retrospective study to see if people that were given drugs hcq or hcq + azt (likely people with worrying/severe form of covid at least enough to prescribe meds) died more than people for which it was decided not to give any particular medicine (likely less severe form of covid ... only 50 were given azt on the no hcq group)...

what were the criteria to give or not hcq ? Were hcq / hcq+azt given with the first symptoms or at an already adavanced stage ?

Comparing deaths between people who seemed really sick (they need medication) with people not needing particular medication is a bit confusing ... conclusions show either lack of analysis or partiality

11 ^ | v 4 • Reply • Share ›

Doctor Hawaii ↗ Udub • 20 hours ago

This isn't a strange study at all.
The purpose is to analyze the risks and benefits of a treatment that is currently getting widespread use despite no good evidence supporting that use. The results of this and RCTs currently occurring should help shape guidance on treatment so that we don't wind up (needlessly) harming or killing more people than we help.
And the clinical characteristics of the patients in each group were accounted for and factored into the results: "...competing risk hazard regression adjusting for clinical characteristics..."

1 ^ | v 4 • Reply • Share ›

Nom DePlume ↗ Udub • 20 hours ago

While is true we don't know how the patients were chosen for who received the meds and who did not, it seems reasonable that the sicker, more desperate were given the meds.

While that would bias the results of higher ventilation and/or death, this study DOES show that the drugs ARE NOT MIRACLE CURES OR GAME CHANGERS.

patients (unlike Birx and Fauci), doctors rated HCQ and Zithromax as the top #1 and #2 drugs in efficacy. (37% HCQ #1, 32% Azithromycin #1).

The effective protocol is already well-established. Drug therapy should begin at the onset of breathing difficulties, not after patients have been placed on ventilators, from which only 20-50% of patients currently survive. Doctors Zelenko and Didier have had success rates of well over 90% when following the standard protocol.

Reply • Share ›

Eric H ➚ Nom DePlume • 10 hours ago

It does not show that at all. It only shows that the study authors used a faulty method (PSM) to account for some non-random factors, while completely ignoring the most obvious and invisible confounding variables, i.e. what was going on in the doctor's mind(s) when the decision was made to prescribe the drugs. Never mind that the drugs were given too late to be of any use and besides, the very critical element zinc was not even mentioned once in the study where the vast majority of the patients were likely zinc deficient (being average age of 65).

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

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