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Growing Evidence Shows COVID-19 Treatments Are Working

Posted by Erik Sass on February 8, 2021 7:52 am
Tags: Covid-19
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Just over a year into the COVID-19 pandemic, multiple drug treatments are finally breaking through the veil of confusion that has obscured these safe, widely used medications. A growing body of evidence supports combinations of oral therapies including ivermectin, hydroxychloroquine (HCQ), doxycycline, azithromycin, steroids, and blood thinners, along with zinc and vitamin D. With vaccines taking time to deploy and having only partial success in high-risk patients, these early outpatient therapies can help manage the disease by lowering mortality and reducing the burden on overstretched healthcare systems.

On January 14 the National Institutes of Health upgraded its drug advisory for ivermectin for COVID-19 from "against" to "neither for nor against," the same status accorded to convalescent plasma and monoclonal antibodies. This is the strongest indication to date from a government authority that early outpatient treatment of COVID-19 may be possible.

The U.S. isn't alone in this shift. In France on January 27, the Council of State, the country's highest court for administrative law, ordered the country's National Medicines Safety Agency to investigate ivermectin for COVID-19, following an appeal by French physicians and medical associations. South Africa allowed ivermectin for COVID-19 the same day. Slovakia became the first country in the EU to officially adopt ivermectin as a treatment for COVID-19, followed by Mexico City, making the drug standard of care for the largest city in the western hemisphere. On January 21 the World Health Organization (WHO) announced that it will begin studying ivermectin as a potential treatment for COVID-19.

Following its unfortunate brush with political controversy, HCQ is getting another hearing. On December 11, the Italian Council of State allowed HCQ for early outpatient treatment of COVID-19, citing a review of early treatment data from around the world; Italian doctors also issued their own COVID-19 treatment guidelines including HCQ. In the U.S., the drug is included in the sequential multidrug therapy protocol recommended by 57 physicians in treatment guidelines published in December, along with ivermectin, azithromycin, doxycycline, and (outside the U.S.) favipiravir.

An ongoing analysis of 196 observational studies and randomized controlled trials (RCTs) of HCQ for COVID-19 shows an average 67% improvement across outcomes including hospitalization and death, while 35 studies of ivermectin, including multiple RCTs, show an average 78% improvement in mortality at the current tally.

HCQ also appears to have significant preventive effect. A meta-analysis of five RCTs, covering a total of 5,577 patients, found a significant (24%) reduction in risk of negative outcomes using a composite measure of COVID-19 infection, hospitalization, and death, rising to 32% when the proper relationship of early HCQ use after COVID-19 exposure in one of the RCTs was used.

The safety of ivermectin and HCQ are well established. Over the last four decades, 3.7 billion doses of ivermectin have been used to treat conditions like roundworm, scabies, and head lice. Since 1955, tens of billions of doses of HCQ and its predecessor chloroquine have been used to treat of malaria. HCQ's most serious potential side effect, QT prolongation affecting the heart's electrical signaling system (also caused by antihistamines, antibiotics and many other common drugs) is easily anticipated and routinely managed by competent physicians. Over 65 years of use, fatality due to HCQ has been vanishingly rare. Regarding COVID-19 specifically, the drug "is safe for a short-term treatment for patients with COVID-19 infection regardless of the clinical setting of delivery," according to a recent study in the European Society of Cardiology's journal, *EP Europace*.

Opposition to HCQ is based on a small pool of "rigorous," "high quality" RCTs that are in fact compromised by flaws – unblinded protocols, therapeutic rather than placebo controls, changing endpoints and early termination, lack of standard testing, small sample sizes, and misrepresentation of statistical significance for magnitude of benefit.

The politics of this pandemic have caused us to buck a century of sound medical practice in which doctors prescribed what they deem best for patients based overwhelmingly on observational studies, not RCTs. Growing evidence from around the world that early treatment options for COVID-19 are preventing hospitalizations and deaths should start to change this.

We hope physicians, scientists and regulators will carefully assess the quality and integrity of all current and future studies to determine what is best for patients.

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