



Coronavirus Disease-2019 (COVID-19) Pandemic - What are we Missing

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In December 2019, China faced the first known case of infection caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and as of June 23, 2020, 8,993,659 cases of the COVID-19 infection have been reported worldwide with 469,587 deaths globally [1]. The past 7 months have seen an unprecedented increase in publications related to a single disease, with 35,444 publications reported on the World Health Organization Global Research Database as of June 23, 2020 [2]. Despite this extraordinary effort by researchers and scientists across the world, no treatment has been proven to be effective so far. Although several trials on developing a vaccine are ongoing, until a safe and effective vaccine is available, the only effective strategy against this disease is mitigating the risk of contracting the infection by measures such as social distancing, hand washing and wearing masks [3].

Hydroxychloroquine was one of the first medications that gained interest as potential treatment for COVID-19. The initial studies from France and China showed efficacy of this anti-malarial agent in improving virological clearance, reducing symptoms, preventing radiographic progression and even reducing mortality [4-6]. However, there were several significant limitations of these studies including small sample sizes, lack of blinding, and lack of control arm and an increased risk of bias. Despite these limitations, several countries approved hydroxychloroquine use for COVID-19 based on these initial studies. Following this initial data, several studies failed to show any efficacy of hydroxychloroquine in COVID-19 [7-9]. However, all of these studies also had several limitations and drawbacks, similar to the initial studies showing efficacy of hydroxychloroquine. As more data poured in, better designed trials such as the RECOVERY trial failed to show any efficacy of hydroxychloroquine as treatment or as prophylaxis of COVID-19

[10,11]. This then led to withdrawal of approval for use of hydroxychloroquine by agencies such as FDA [12].

This story of rise and fall of hydroxychloroquine in COVID-19 teaches us the importance of well-designed clinical trials in medicine. Randomized, controlled, double-blinded clinical trials are the foundation of clinical research and development of effective diagnostic and therapeutic strategies in medicine. Although no research is without a flaw, performing a well-designed clinical trial is an art with which the medical community across the world is well equipped, as has been proven time and again in the past. A researcher is always aware of the limitations of his/her study, and it is the recognition of our own limitations that leads us to the path of continuous improvement in the field of science. Understandably, the world faces unprecedented times in the midst of this pandemic. Time is of essence in saving lives, and performing clinical trials is a time-consuming process. While studies showing potential efficacy of an agent can raise hope, population-wide recommendations shall best be avoided until the limitations of such trials are acknowledged, and we have well-designed clinical trials confirming the findings of any preliminary data.

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