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Opinion on double strategy to fight COVID-19: vaccination and home treatment with

non-steroidal anti-inflammatory drugs

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Abstract

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Usually, the goals of global vaccination are to control, eliminate, or eradicate infectious diseases in a sustainable way that strengthens health. Although the use of vaccines is essential for the control of epidemics, the vaccines against COVID-19 proved to be inadequate to end the pandemic and must be considered incomplete. Unfortunately, these vaccines failed to prevent infection, so their primary purpose became to prevent severe disease and, possibly, hospitalizations and deaths. Therefore, we believe that all the strategies available to fight transmission, hospitalizations and deaths due to COVID-19 must be put in place. According to scientific knowledge, uncontrolled inflammation and thrombosis are the principal mechanisms for aggravation and death in patients with COVID-19 (3). Unlike corticosteroids that should not be administered at the beginning of the symptoms for their immunosuppressive action, that could get worse the evolution of the disease, the observation that make non-steroidal antiinflammatory drugs (NSAIDs) useful in the early at home treatment of the disease is becoming more and more evident.

INTRODUCTION

In a recent manuscript regarding COVID-19 vaccinations, the authors stated that "current vaccines provide only modest protection against infection and transmission with omicron variant, even at peak immunity after boosting", that "boosting every 4 to 6 mo to maintain high serum neutralizing antibody titers may not be a practical or desirable long-term strategy" and that "boosting with mRNA vaccines is also not risk free" (1).

Usually, the goals of global vaccination are to control, eliminate, or eradicate infectious diseases in a sustainable way that strengthens health systems. Although the use of vaccines is essential for the control of epidemics, the vaccines against COVID-19 proved to be inadequate to end the pandemic and must be considered incomplete. Unfortunately, these vaccines failed to prevent infection, so their primary purpose became to prevent severe disease and, possibly, hospitalizations and deaths. Therefore, we believe that all the strategies available to fight transmission, hospitalizations and deaths due to COVID-19 must be put in place.

## MAIN TEXT

at the beginning of pandemic, we expressed the opinion that it is not ethical to leave the patients with covid-19 without any treatment, waiting certainties to be established by evidence-based medicine, and, among the various drugs that we could have used, we suggested indomethacin for its peculiar mechanisms (2). now, we believe that vaccination and early at home pharmacologic treatment should be used together to fight sars-cov-2 pandemic. pharmacologic treatment should be possibly simple and cheap, and be carried out promptly at home by most of world population, especially where population has not access to vaccines and to the expensive approved antivirals. according to scientific knowledge, uncontrolled inflammation and thrombosis are the principal mechanisms for aggravation and death in patients with covid-19 (3). unlike corticosteroids, that should not be administered at the beginning of the symptoms for their immunosuppressive action, that could get worse the evolution of the disease, it is becaming more and more evident that non-steroidal anti-inflammatory drugs (nsaids)

are indicated in the early at home treatment of the disease. unfortunately, at the beginning of pandemic, also nsaids were discouraged because of fears they would result in a worsening of the disease with their use in the early phase (4), but recently perico et al, in their review published in lancet infectious diseases, have reported that nsaids, in particular selective anti cox2 drugs and indomethacin may be very useful in the treatment of covid-19 (5). this latter, probably, for its anti-inflammatory, antiviral and anti-platelet properties (6). indomethacin has shown a very good efficacy, in a randomized controlled study, in comparison with paracetamol, by greatly reducing the percentage of patients who desaturated (spo2≤93), in the course of the disease, from 20% in the group paracetamol to 0% in the group indomethacin (7). in addition, our group showed that a treatment of covid-19 patients with indomethacin plus cardioaspirin, started within the first 3 days of onset of symptoms, set to zero hospitalizations, reduced significantly the symptom duration and the number of patients who had increased d-dimer after polymerase chain reaction negativization and complete recovery, in comparison with a comparable group of patients who started the same treatment after 3 days (8).

in a further retrospective observational study we confirmed the significant reduction of hospitalizations not only with indomethacin, but also with other nsaids, in a group of over 50 years old patients (mean age 60+9 years) treated early at home for covid-19 (9). consolaro *et al* have shown that a home-treatment algorithm based on anti-inflammatory drugs prevented hospitalization of patients with early covid-19 (10). another recent manuscript by cosentino *et al*, reporting the results of a retrospective analysis of 392 cases of covid-19 in italy, early treated at home mainly with nsaids, shows very low number of hospitalizations (5.8%) and lethality (0.2%) (11).

all together, these studies, although most of them with an observational design, consistently\_indicate that prompt therapy at home with nsaids may be very beneficial in patients with mild to moderate covid-19 (5,7-11). in the past, when several observational studies consistently showed the same beneficial result, promptly randomized controlled

trials were performed to assess the rightness of the result. on this occasion, however inexplicably, this was not done.

Main text

## **CONCLUSION**

We hope that prospective randomized controlled trials on the efficacy of early at home treatment with NSAIDs in patients with mild to moderate COVID-19, also with a design of non-inferiority compared to the antiviral drugs currently authorized for treatment, start as soon as possible. The demonstration of NSAIDs' efficacy in the therapy of COVID-19 would make available drugs well known, easy accessible, and cheap, with a great saving in health care spending.

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