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Letter to Editor

Experience on Home Treatment of COVID-19 Patients with the Association of Hydroxychloroquine (HCQ) and Azithromycin (AZM) During the Peak of the Pandemic in Bergamo (Italy) -

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KEYWORDS

COVID-19; Peak of pandemic; Hydroxychloroquine; Azithromycin; Home treatment; Safety

INTRODUCTION

In December 2019, a novel coronavirus (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]) emerged in China and has spread globally, creating a pandemic. Lombardy, a northern Italy region, is one of the most productive regions in Europe, with strong international links and a high-density population. These facts could justify the high cost in terms of infected people and deaths [1,2].

Among the possible treatments of COVID-19 patients, the Hydroxychloroquine (HCQ) alone or in association was proposed as a potential therapeutic option [3,4]. It is known that choloroquine and hydroxychloroquine are currently used to treat malaria and rheumatoid conditions. This drug demonstrated antiviral activity in different studies and ability to modify the immune system. These evidences led to the hypothesis that it could also be useful in the treatment of COVID-19. Therefore, in Italy, the indication of the use of HCQ in COVID-19 patients was reported by the guidelines of the Italian Society of Infectious and Tropical Diseases published on 13 March 2020 [5]. This in spite of the fact that this drug is not without risk of toxicity (cardiac arrhythmias, seizures, dermatitis and hypoglycemia). On March 17 2020 the Agenzia Italiana Del Farmaco (AIFA) introduced the off-label use of HCQ for the treatment of SARS-COV-2 infection to the list of treatments reimbursed by the National Health System [6].

In the period of March-April 2020 in the area of Bergamo we registered an unexpected outbreak of COVID-19, and the Emergency Department of Humanitas Gavazzeni had to face a tremendous overload of patients [7]. More than thousand patients referred to this Hospital during the peak of COVID-19 pandemic. The majority with severe disease was admitted into COVID Department and Intensive Care Unit. From 11th March to 24th April 352 Covid-19 patients were discharged without hospitalization. Of them, 78 patients were treated at home with oral association of Hydroxychloroquine (HCQ) and Azithromycin (AZM).

In the following time, the analysis of the international scientific data from the emergency use of HCQ in treating COVID-19, determined HCQ unlikely to be effective for COVID-19 and the drug was identified as possible cause of serious cardiac adverse events. On this basis, FDA revoked the emergency use authorization for chloroquine and hydroxychloroquine. In Italy AIFA suspended the authorization of the use of HCQ for the treatment of SARS-Cov-2 infection outside clinical trials [8].

Considering this complex and dynamic scenario, we would like to briefly report our experience of home treatment of 78 COVID-19 patients with the association of HCQ and AZM, limited in the period above indicated, before the authorization was suspended.

All 78 patients underwent therapy after laboratory tests (with particular attention to the kidney function), nasopharyngeal swabs for SARS-COV-2, ECG with QT evaluation in order to exclude toxic effects. The treatment consisted in HCQ 400 mg BID on 1st day followed by 200 mg BID for 6 days associated to AZM 500 mg daily for 6-7 days [9].

The median age of the treated patients was 57 years, 43 (55.1%) patients were male and 35 (44.9%) female. The mean of oxygen saturation at the time of admission to the Emergency Room was 96%. The swab tests positive were 50 of 78 (64.1%) and the negative ones were 28 of 78 (35.9%).

We lost the follow-up of 3 (3.8%) patients, while we kept 75 (96.2%) patients on active telephone follow-up. Only 18 out of 75 (24%) had a second access to Emergency Department: 10 patients were discharged, while 8 patients were hospitalized for treatment.

At the last evaluation on 30th April 2020, only one patient resulted still hospitalized. A complete clinical recovery was described in 63 (84%) patients and, of these, 31 (41.3%) resulted clinically cured even if their swab tests were still positive. We would like to stress that among this group of patients treated with the combination of HCQ with AZM none had to stop the therapy or showed some relevant side effects, although it was not possible to evaluate QT at the end of treatment [Table 1].

Table 1: Results of home treatment of 78 patients with HCQ and HZM.

	Overall ***N* = 78**
Median age	57 years
Sex	
Male	43 (55.1%)
Female	35 (44.9%)
SARS-COV-2 swab	
Positive	50 (64.1%)
Negative	28 (35.9%)
Telephone follow-up	
Active	75 (96.2%)
Lost	3 (3.8%)
Side effects	
No	75 (100%)
Yes	0 (0%)
Outcome	
Improvement/recovery	63 (84%)
Second access to ED	18 (24%)
Still hospitalized	1 (1.3%)
Follow-up period: from 11th March to 24th April 2020.	

Among the 274 discharged patients without any prescription of HCQ plus AZM, at the last evaluation on 30th April 193 (70%) showed a complete clinical recovery and in 30 patients, even if clinically cured, the swab test was still positive.

This retrospective observation on a small series of patients, with a very short follow-up, of course does not presume to demonstrate that the combination of HCQ and AZM should be always considered an effective therapy for COVID-19. However, it is interesting to note that on our group of patients discharged from the hospital, this combined treatment gave favorable results and its home management was easy with the collaboration of the general practitioner. About the safety we can say, that during the period of treatment, the side effects resulted negligible, including cardiac ones. Unfortunately, we have no data on the effects in the medium-long term, lacking the necessary controls.

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