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LAMPIRAN

Lampiran 1. Artikel : Safety and effectiveness of azithromycin in patients with COVID-19: An open-label randomised trial

International Journal of Antimicrobial Agents 56 (2020) 106143

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Safety and effectiveness of azithromycin in patients with COVID-19: An open-label randomised trial

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Keywords:
COVID-19
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Azithromycin
Hydroxychloroquine
Lopinavir
Ritonavir

ABSTRACT

As no specific pharmacological treatment has been validated for use in coronavirus disease 2019 (COVID-19), we aimed to assess the effectiveness of azithromycin (AZM) in these patients at a referral centre in Iran. An open-label, randomised controlled trial was conducted on patients with laboratory-confirmed COVID-19. A total of 55 patients in the control group receiving hydroxychloroquine (HCQ) and lopinavir/ritonavir (LPV/r) were compared with 50 patients in the case group who in addition to the same regimen also received AZM. Patients with prior cardiac disease were excluded from the study. Furthermore, patients from the case group were assessed for cardiac arrythmia risk based on the American College of Cardiology (ACC) risk assessment for use of AZM and HCQ. The main outcome measures were vital signs, SpO_2 levels, duration of hospitalisation, need for and length of intensive care unit admission, mortality rate and results of 30-day follow-up after discharge. Initially, there was no significant difference between the general conditions and vital signs of the two groups. The SpO_2 levels at discharge were significantly higher, the respiratory rate was lower and the duration of admission was shorter in the case group. There was no significant difference in the mortality rate between the two groups. Patients who received AZM in addition to HCQ and LPV/r had a better general condition. HCQ+AZM combination may be beneficial for individuals who are known to have a very low underlying risk for cardiac arrhythmia based on the ACC criteria.

1. Introduction

In late December 2019, an outbreak of an emerging disease with a remarkably high virulence in Wuhan, China, soon became a global concern. Disease symptoms resemble a viral pneumonia and genetic analysis of lower respiratory tract samples of early infected patients showed an infection caused by the novel coronavirus 2019-nCoV, subsequently named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes coronavirus disease 2019 (COVID-19). The disease rapidly spread throughout China and infected multiple other countries [1,2]. On 12 March 2020, the World Health Organization (WHO) declared the epidemic

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Lampiran 2. Artikel : Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial

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Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial ☆

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ARTICLE INFO

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Key words:
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Azithromycin
Clinical trial

ABSTRACT

Background: Chloroquine and hydroxychloroquine have been found to be efficient on SARS-CoV-2, and reported to be efficient in Chinese COV-19 patients. We evaluate the effect of hydroxychloroquine on respiratory viral loads.

Patients and methods: French Confirmed COVID-19 patients were included in a single arm protocol from early March to March 16th, to receive 600mg of hydroxychloroquine daily and their viral load in nasopharyngeal swabs was tested daily in a hospital setting. Depending on their clinical presentation, azithromycin was added to the treatment. Untreated patients from another center and cases refusing the protocol were included as negative controls. Presence and absence of virus at Day6-post inclusion was considered the end point.

Results: Six patients were asymptomatic, 22 had upper respiratory tract infection symptoms and eight had lower respiratory tract infection symptoms.

Twenty cases were treated in this study and showed a significant reduction of the viral carriage at D6-post inclusion compared to controls, and much lower average carrying duration than reported in the litterature for untreated patients. Azithromycin added to hydroxychloroquine was significantly more efficient for virus elimination.

Conclusion: Despite its small sample size, our survey shows that hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in COVID-19 patients and its effect is reinforced by azithromycin.

1. Introduction

In late December 2019, an outbreak of an emerging disease (COVID-19) due to a novel coronavirus (later named SARS-CoV-2) started in Wuhan, China and rapidly spread in China and outside [1,2]. The WHO declared the epidemic of COVID-19 as a pandemic on March 12th 2020 [3]. According to a recent Chinese study,

☆ Given his role as Editor in Chief of this journal, Jean Marc Rolain had no involvement in the peer-review of this article and has no access to information regarding its peer-review. Full responsibility for the peer-review process for this article was delegated to P.R. Hsueh.

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Lampiran 3. Artikel : Clinical and microbiological effect of a combination of hydroxychloroquine and azithromycin in 80 COVID-19 patients with at least a six-day follow up: A pilot observational study

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Original article

Clinical and microbiological effect of a combination of hydroxychloroquine and azithromycin in 80 COVID-19 patients with at least a six-day follow up: A pilot observational study

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Keywords:
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Hydroxychloroquine
Azithromycin
PCR
Culture

ABSTRACT

Background: We need an effective treatment to cure COVID-19 patients and to decrease virus carriage duration.
Methods: We conducted an uncontrolled, non-comparative, observational study in a cohort of 80 relatively mildly infected inpatients treated with a combination of hydroxychloroquine and azithromycin over a period of at least three days, with three main measurements: clinical outcome, contagiousness as assessed by PCR and culture, and length of stay in infectious disease unit (IDU).
Results: All patients improved clinically except one 86 year-old patient who died, and one 74 year-old patient still in intensive care. A rapid fall of nasopharyngeal viral load was noted, with 83% negative at Day7, and 93% at Day8. Virus cultures from patient respiratory samples were negative in 97.5% of patients at Day5. Consequently patients were able to be rapidly discharged from IDU with a mean length of stay of five days.
Conclusion: We believe there is urgency to evaluate the effectiveness of this potentially-life saving therapeutic strategy at a larger scale, both to treat and cure patients at an early stage before irreversible severe respiratory complications take hold and to decrease duration of carriage and avoid the spread of the disease. Furthermore, the cost of treatment is negligible.

1. Introduction

In late December 2019, an outbreak of an emerging disease (COVID-19) due to a novel coronavirus (named SARS-CoV-2 latter) began in Wuhan, China and quickly spread in a substantial number of countries [1,2]. The epidemic was declared a pandemic by the WHO on March 12, 2020 [3]. According to a Chinese study, 80% of patients present with mild symptoms and the overall fatality rate is about 2.3%, although this rises to 8.0% in

The paper was accepted based on six peer reviews previously conducted for another journal.

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Lampiran 4. Artikel : Early treatment of COVID-19 patients with hydroxychloroquine and azithromycin: A retrospective analysis of 1061 cases in Marseille, France

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Early treatment of COVID-19 patients with hydroxychloroquine and azithromycin: A retrospective analysis of 1061 cases in Marseille, France

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ARTICLE INFO

Keywords:
SARS-CoV-2
COVID-19
Hydroxychloroquine
Azithromycin

ABSTRACT

Background: In France, the combination hydroxychloroquine (HCQ) and azithromycin (AZ) is used in the treatment of COVID-19.

Methods: We retrospectively report on 1061 SARS-CoV-2 positive tested patients treated for at least three days with the following regimen: HCQ (200 mg three times daily for ten days) + AZ (500 mg on day 1 followed by 250 mg daily for the next four days). Outcomes were death, clinical worsening (transfer to ICU, and > 10 day hospitalization) and viral shedding persistence (> 10 days).

Results: A total of 1061 patients were included in this analysis (46.4% male, mean age 43.6 years – range 14–95 years). Good clinical outcome and virological cure were obtained in 973 patients within 10 days (91.7%). Prolonged viral carriage was observed in 47 patients (4.4%) and was associated to a higher viral load at diagnosis ($p < .001$) but viral culture was negative at day 10. All but one, were PCR-cleared at day 15. A poor clinical outcome (PClinO) was observed for 46 patients (4.3%) and 8 died (0.75%) (74–95 years old). All deaths resulted from respiratory failure and not from cardiac toxicity. Five patients are still hospitalized (98.7% of patients cured so far). PClinO was associated with older age (OR 1.11), severity of illness at admission (OR 10.05) and low HCQ serum concentration. PClinO was independently associated with the use of selective beta-blocking agents and angiotensin II receptor blockers ($p < .05$). A total of 2.3% of patients reported mild adverse events (gastrointestinal or skin symptoms, headache, insomnia and transient blurred vision).

Conclusion: Administration of the HCQ + AZ combination before COVID-19 complications occur is safe and associated with a very low fatality rate in patients.

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Lampiran 5. Artikel : Association of Treatment With Hydroxychloroquine or Azithromycin With In-Hospital Mortality in Patients With COVID-19 in New York State

JAMA | Original Investigation

Association of Treatment With Hydroxychloroquine or Azithromycin With In-Hospital Mortality in Patients With COVID-19 in New York State

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IMPORTANCE Hydroxychloroquine, with or without azithromycin, has been considered as a possible therapeutic agent for patients with coronavirus disease 2019 (COVID-19). However, there are limited data on efficacy and associated adverse events.

OBJECTIVE To describe the association between use of hydroxychloroquine, with or without azithromycin, and clinical outcomes among hospital inpatients diagnosed with COVID-19.

DESIGN, SETTING, AND PARTICIPANTS Retrospective multicenter cohort study of patients from a random sample of all admitted patients with laboratory-confirmed COVID-19 in 25 hospitals, representing 88.2% of patients with COVID-19 in the New York metropolitan region. Eligible patients were admitted for at least 24 hours between March 15 and 28, 2020. Medications, preexisting conditions, clinical measures on admission, outcomes, and adverse events were abstracted from medical records. The date of final follow-up was April 24, 2020.

EXPOSURES Receipt of both hydroxychloroquine and azithromycin, hydroxychloroquine alone, azithromycin alone, or neither.

MAIN OUTCOMES AND MEASURES Primary outcome was in-hospital mortality. Secondary outcomes were cardiac arrest and abnormal electrocardiogram findings (arrhythmia or QT prolongation).

RESULTS Among 1438 hospitalized patients with a diagnosis of COVID-19 (858 [59.7%] male, median age, 63 years), those receiving hydroxychloroquine, azithromycin, or both were more likely than those not receiving either drug to have diabetes, respiratory rate >22/min, abnormal chest imaging findings, O_2 saturation lower than 90%, and aspartate aminotransferase greater than 40 U/L. Overall in-hospital mortality was 20.3% (95% CI, 18.2%-22.4%). The probability of death for patients receiving hydroxychloroquine + azithromycin was 189/735 (25.7% [95% CI, 22.3%-28.9%]), hydroxychloroquine alone, 54/271 (19.9% [95% CI, 15.2%-24.7%]), azithromycin alone, 21/211 (10.0% [95% CI, 5.9%-14.0%]), and neither drug, 28/221 (12.7% [95% CI, 8.3%-17.1%]). In adjusted Cox proportional hazards models, compared with patients receiving neither drug, there were no significant differences in mortality for patients receiving hydroxychloroquine + azithromycin (HR, 1.35 [95% CI, 0.76-2.40]), hydroxychloroquine alone (HR, 1.08 [95% CI, 0.63-1.85]), or azithromycin alone (HR, 0.56 [95% CI, 0.26-1.21]). In logistic models, compared with patients receiving neither drug cardiac arrest was significantly more likely in patients receiving hydroxychloroquine + azithromycin (adjusted OR, 2.13 [95% CI, 1.12-4.05]), but not hydroxychloroquine alone (adjusted OR, 1.91 [95% CI, 0.96-3.81]) or azithromycin alone (adjusted OR, 0.64 [95% CI, 0.27-1.56]), . In adjusted logistic regression models, there were no significant differences in the relative likelihood of abnormal electrocardiogram findings.

CONCLUSIONS AND RELEVANCE Among patients hospitalized in metropolitan New York with COVID-19, treatment with hydroxychloroquine, azithromycin, or both, compared with neither treatment, was not significantly associated with differences in in-hospital mortality. However, the interpretation of these findings may be limited by the observational design.

Related article page 2518

Supplemental content

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Lampiran 6. Kartu Laporan Pertemuan Bimbingan KTI

POLITEKNIK KESEHATAN
JURUSAN FARMASI
JL. AIRLANGGA NO. 20 MEDAN

KARTU LAPORAN PERTEMUAN BIMBINGAN KTI MAHASISWA TA. 2020/2021

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NO	TGL	PERTEMUAN	PEMBAHASAN	PARAF MAHASISWA	PARAF PEMBIMBING
1	27/a/21	zoom	Pengojuan Judul		
2	29/01/21	Zoom	Persetujuan Judul		
3	26/02/21	g. meet	Bimbingan BaB I-III		
4	27/02/21	WA group	Perbaikan BaB I-III		
5	28/02/21	WA group	Perbaikan BAB I-III		
6	8/03/21	CP WA	REVISI SEMPRO		
7	4/04/21	Tatap muka	menandatangani EC		
8	7/05/21	Tatap muka	REVISI BAB I-V		
9	11/05/21	CP WA	Pengiriman File dan Artikel		
10	16/05/21	Tatap muka	REVISI KTI		
11	17/05/21	Tatap muka	REVISI KTI		
12	18/05/21	Tatap muka	REVISI KTI		

Ketua,

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