Using Real World Evidence on Repurposed Drugs to Inform Future Clinical Trials to Treat COVID-19

Reema Charles1; Parvesh Paul1; Heather Stone2; Katarzyna Borkowski2; Belinda Nhundu2; Paige Evans3; Eleanor McCartney1; Holly Graber2; Maggie McCoy1; Mili Duggal2; Leonard Sacks2; Noel Southall2; Marco Schito1; Serghei Gorobet2; Dominic Nieves3; Timothy Sheils3; Ruby Geng3; Marco Garcia Aviles3

Author Affiliations: 1C-Path, 2FDA, 3NCATS/NIH

Introduction

CURE ID is an internet-based data repository developed collaboratively by FDA and NCATS/NIH, with the support of WHO and IDSA. It is a mobile application and website, designed to capture real-world clinical outcome data to advance drug repurposing and inform future clinical trials for diseases of high unmet medical need. It also serves as a rapid communication platform for healthcare providers during an outbreak, providing for case-sharing and discussion. This descriptive analysis portrays the drugs reported in the treatment of patients with COVID-19 thus far on the CURE ID platform.

Materials and Methods

We extracted individual case reports of treatments and outcomes from published peer-reviewed literature, user submitted case reports, and from the University of Pennsylvania’s CORONA database to further populate the CURE ID database. Case reports were uploaded in the app by using Standard Operating Procedures (SOPs) that ensured data uniformity and standardization.

Results

As of April 2021, a total of 1109 COVID-19 case reports, treated with 239 different drugs have been included in the CURE ID platform. Majority (58%) of the reported cases were in males. Hypertension and diabetes mellitus were the most frequently reported comorbidities. Hydroxychloroquine (n=526), Lopinavir-Ritonavir (n=350), Azithromycin (n=289), Tocilizumab (n=161) and Methylprednisolone (n=153) were the most frequently reported drugs. Only 34% of the cases reported severity of patient’s illness, out of which 226 were inpatients, 142 ICU/critical care and 11 were outpatients. Deaths ranged from 3% – 20% across all drugs, with a total mortality rate of 16% in the sample.

Reported therapeutic categories (based on proposed mechanism of action) included antivirals, antibiotics, immune modulators, corticosteroids, anticoagulants and others (Figure 3).

Results and Discussion (continued)

Figure 1. Distribution by Patient Characteristics

Figure 2. Distribution of Drugs Reported by Treatment Setting

Figure 3. Breakdown of Drugs Utilized by Category

Conclusion

We extracted individual case reports of treatments and outcomes based upon severity of COVID-19 disease presentation from published peer-reviewed literature, user submitted case reports, and from the University of Pennsylvania’s CORONA database to further populate the CURE ID database.

Case reports were gathered on patients from more than 40 different countries, in all regions of the world. More than 200 drugs have been repurposed in an attempt to treat patients with COVID-19.

No conclusions about the efficacy of these drugs can be drawn based upon this data, given the high spontaneous recovery rates for this illness and the lack of adequately controlled studies.

Acknowledgements

The authors would like to thank Dr. David Fajgenbaum and the members of the CORONA database group for their assistance in identifying the articles to be included.

Disclaimer

This poster reflects the views of the authors and should not be construed to represent NIH or FDA’s views or policies.

Author Affiliations: 1C-Path, 2FDA, 3NCATS/NIH

Materials and Methods

We extracted individual case reports of treatments and outcomes from published peer-reviewed literature, user submitted case reports, and from the University of Pennsylvania’s CORONA database to further populate the CURE ID database. Case reports were uploaded in the app by using Standard Operating Procedures (SOPs) that ensured data uniformity and standardization.

Results

As of April 2021, a total of 1109 COVID-19 case reports, treated with 239 different drugs have been included in the CURE ID platform. Majority (58%) of the reported cases were in males. Hypertension and diabetes mellitus were the most frequently reported comorbidities. Hydroxychloroquine (n=526), Lopinavir-Ritonavir (n=350), Azithromycin (n=289), Tocilizumab (n=161) and Methylprednisolone (n=153) were the most frequently reported drugs. Only 34% of the cases reported severity of patient’s illness, out of which 226 were inpatients, 142 ICU/critical care and 11 were outpatients. Deaths ranged from 3% – 20% across all drugs, with a total mortality rate of 16% in the sample.

Reported therapeutic categories (based on proposed mechanism of action) included antivirals, antibiotics, immune modulators, corticosteroids, anticoagulants and others (Figure 3).

Results and Discussion (continued)

Figure 1. Distribution by Patient Characteristics

Figure 2. Distribution of Drugs Reported by Treatment Setting

Figure 3. Breakdown of Drugs Utilized by Category

Conclusion

We extracted individual case reports of treatments and outcomes based upon severity of COVID-19 disease presentation from published peer-reviewed literature, user submitted case reports, and from the University of Pennsylvania’s CORONA database to further populate the CURE ID database.

Case reports were gathered on patients from more than 40 different countries, in all regions of the world. More than 200 drugs have been repurposed in an attempt to treat patients with COVID-19.

No conclusions about the efficacy of these drugs can be drawn based upon this data, given the high spontaneous recovery rates for this illness and the lack of adequately controlled studies.

Acknowledgements

The authors would like to thank Dr. David Fajgenbaum and the members of the CORONA database group for their assistance in identifying the articles to be included.

Disclaimer

This poster reflects the views of the authors and should not be construed to represent NIH or FDA’s views or policies.