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Study of Drug Utilization Pattern during Second Wave of Covid-19 in a Tertiary Care Centre: A Retrospective Cross Sectional Study

Ujwala P. Gawali*, Aruna Gurung

Department of Pharmacology, Dr. Vaishyampayan Memorial Government Medical College, Solpaur, Maharashtra, India.

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ABSTRACT

Background: To study the drug utilization trends among patients with COVID-19 disease during the second wave in a tertiary care hospital.

Methods: A retrospective cross-sectional study was conducted in patients admitted in COVID-19 wards during second wave of SARS – COVID-19 pandemic from 1st March 2021 to 30th June 2021. A total of 300 prescriptions were analysed. Assessment of prescription patterns were done as per the WHO-The International Network for Rational Use of Drugs (INRUD)drug use indicators.

Results: A total of 3106 drugs were analysed.The average number of drugs prescribed was 11±5.1. The most frequent prescription was that of analgesic and antipyretic drug Paracetamol (95.26%) followed by vitamin C (94.74%) and multivitamins(87.89%) . Nearly all patients in this study received antibacterials, 68% received antivirals. Antibacterials commonly used were cephalosporins, amoxicillin- clavulanic acid combination and pipercillin –tazobactam combination. Antiviral drug Remdesivir was also used extensively in our study (54.21%). Other class of drugs which were commonly prescribed to more patients were Dalteparin (73.16%) and corticosteroids like methyl prednisolone (52.63%) and dexamethasone (51.05%). 35.68% of the drugs were prescribed with generic name .45.43% of the drugs were injectables . 2.96% of the drugs were prescribed as fixed dose combinations.

Conclusion: In summary, the drug utilization for hospitalized patients with COVID-19 was diverse but generally complied with the ongoing guidelines. The drug were mostly prescribed from WHO essential drug list and percentage of fixed dose combination prescription was low. However not prescribing the drugs by generic name and large encounters of injectable was matter of concern. To get a better glimpse of drug utilization a more extensive study needs to be undertaken.

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Introduction

Coronavirus Disease 2019 (COVID-19) is the disease caused by a new coronavirus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The first case of SARS-CoV-2 was detected on 31 December 2019, following a report of a cluster of cases of 'viral pneumonia' in Wuhan, People's Republic of China (1). In India the first case of SARS-COVID-2 was reported in Kerela in January 30 2020. Subsequently the cases rapidly rose increasing the death toll in India. By the January 2021 the cases had started to decline only to show a more fatal second peak which started from March 2021. Maharashtra was severely affected in both first and second wave the first case in Maharashtra was reported on 9 March 2020 (2).

Like the first wave, the second wave of COVID-19 which started from the end of February 2021 and lasted till June 2021 had severe consequences in the form of spiralling

*Corresponding Author: Dr Ujwala P. Gawali
Address:Department of Pharmacology, Dr. Vaishyampayan Memorial Government Medical College, Solpaur, Maharashtra, India. Tel: +2172749405, 7058102055.
Email:arunagurung11@yahoo.co.in

cases, reduced supplies of essential treatments, and increased deaths particularly in the young population (3).
Many studies identified various circulating double-mutant and triple mutant strains of SARS-CoV-2 across different regions of India, during the second wave which were more pathogenic than the initial strains. Also the cases of mucormycosis, which were alarmingly reported in COVID patients with diabetes, as well as patients who were recovering from infection lead to severe panic among the people and health care workers (4).

The mass vaccination programme started before the beginning of second wave in patient above 18 years of age. Still the rise in number of cases and non-availability of specific anti-viral treatment posed a serious concern in the management of COVID-19 (5).
Several treatment strategies were used for the treatment of SARS-COV-2 which included convalescent plasma, interferons (IFN), as well as interleukin 6 receptor inhibitors to inhibit the cytokine storm. Chloroquine and hydroxychloroquine that inhibit endocytosis-mediated viral entry, inhibit endosomal acidification, and disrupt glycosylation of angiotensin converting enzyme 2 (ACE2), as well as ivermectin that inhibits nuclear transport of viral proteins, have also been used to treat COVID-19. In addition, antivirals that inhibit protease inhibitors and nucleotide or nucleoside analogues as well as inhibit viral RNA synthesis were also repurposed for the treatment of the SARS-CoV-2 infection (6- 9).
Nucleoside analogues like remdesivir represented a group of drugs that inhibit reverse transcription and were thought to be the most potent antiviral agents available to combat the SARS-CoV-2 infection but there was very little evidence to prove the efficacy of remdesivir in the treatment of COVID-19 infection and hence, the use of remdesivir gradually declined over the end of second wave (10- 13).
Since multiple drugs have been advocated in a trial and error basis from the start of COVID-19 disease, hence this study is an attempt to know the drug utilization trends among patients with COVID-19 disease during the second wave in our tertiary care hospital.

Methods

A retrospective cross-sectional, observational study was conducted from 1st March 2021-30th August 2021 at Dr.V.M.Govt. Medical College, Solapur. The study was approved by institutional Ethics Committee. The data used in this study are available and will be provided by the corresponding author on a reasonable request.
A total of 300 samples were taken. Sample size was calculated by using the formula 4pq/l2 .Patients with a positive laboratory finding confirming infection with SARS-CoV-2 admitted in our tertiary care hospital during the study period. A positive laboratory finding for SARS-CoV-2 was defined as a positive result on a real time reverse-transcriptase polymerase chain reaction assay (RT-PCR assay) or Rapid Antigen test (RAT) of nasal or pharyngeal swab specimens. Those with negative or indeterminate results for SARS-CoV-2 was excluded from the study.
The prescriptions of COVID-19 positive patients were analysed after getting permission from the Institutional Ethics Committee (IEC). The Strengthening and Reporting of Observational Studies in Epidemiology (STROBE) guidelines were used in the preparation of protocol and the manuscript (14).
Patient are categorized on the basis of severity as mild , moderate and severe cases based on their clinical presentation and Chest CT severity score (CT-SS) (6,15).
Following data records of COVID-19 positive patients were collected for analysis:

1)Demographic profile of the patients i.e. age and sex
2)Prescription details like date, number of drugs, names of individual drugs (generic/brand), any Fixed Dose Combination (FDC) prescribed, dose, dosage form, dosing schedule, and duration of treatment.

Drug utilization both during the stay of the patient in the hospital and during discharge was calculated.
The data analysis was done as follows:
Assessment of prescription patterns were done as per the WHO-INRUD (WHO-International Network for Rational Use of Drugs (INRUD)) drug use indicators which include: (6,16,17)

1) Average number of drugs per encounter
2) Percentage of drugs prescribed by generic name
3) Percentage of encounters with antibiotic
4) Percentage of encounters with injections
5) Percentage of drugs from WHO list of essential medicines
6) Percentage of fixed dose combinations used

Data was filled in Microsoft excel and results was expressed in percentage and mean± standard deviation.

Results

A total of 300 prescriptions of COVID-19 positive patients admitted to COVID-19 wards from 1st March 2021 to 30th June 2021 were analysed. Out of 300 patients 165 (55%) patient were mild COVID-19 cases, 128 (42.7%) were moderate COVID-19 cases and 7 (2.3% were severe COVID-19 cases).

Table 1. Age and sex wise distribution according to the severity of COVID -19 patients.

AGE	Male(n=190)				Female(n=110)				
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	Total Male and Female (%)
10-20	9	2	0	11	4	2	0	6	17(5.67)
21-30	20	4	0	24	10	6	0	16	40(13.33)
31-40	25	15	0	40	6	6	1	13	53(17.67)
41-50	25	11	0	36	19	4	0	23	59(19.67)
51-60	20	15	0	35	10	11	0	21	56(18.67)
61-70	10	20	1	31	5	15	0	20	51(17)
71-80	2	5	4	11	0	10	0	9	20(6.67)
>80	0	1	1	2	0	1	0	2	4(1.33)
Total	**111**	**73**	**6**	**190**	**54**	**55**	**1**	**110**	**300**

The median age was 50 ±17.5 years. The mean duration of stay in the hospital was 10.8±4.9 days.

Out of 300 patients all mild cases i.e. 165 (55%) cases were admitted to COVID-19 isolation ward, all moderate cases i.e. 128 (42.77) cases were admitted to COVID-19 intensive care unit (ICU) and all severe cases i.e. 7 (2.33) cases were admitted to high dependency unit (HDU).

Around 45.8% of the patient had associated comorbid illness. Out of which the most common comorbidity was Diabetes Mellitus (15.3%) followed by Hypertension (12.6%) hypothyroidism (7%), and Ischaemic heart disease(5.3%).Other associated comorbidities were Mucormycosis (2.7%), chronic obstructive pulmonary disease(1.9%), Acute Myeloid leukaemia (0.67%), anti-retroviral disease(0.67%) and pulmonary Koch's (0.33%).

A total of 3106 drugs were prescribed in total. Majority of the drug prescribed was tablet Paracetamol which was prescribed to 95.3% patient followed by Vitamin C prescribed to 94.7% and multivitamin combination of Vitamin A, D and E which was prescribed to .87.9% patients. Antibiotics were prescribed to all the patients. Cephalosporins like ceftriaxone (56.9% to mild cases and 33.5% in moderate cases), cefixime (40% to mild cases and 60% to moderate cases) and co-amoxiclav (83.3% to mild cases and 16.7% to moderate cases) were prescribed mostly to mild and moderate case whereas Piperacillin + Ticarcillin combinations (44%)was prescribed mostly in severe COVID-19 cases. Doxycyline was the most common antibiotic prescribed. Inj. Remdesivir was prescribed in 54.2% cases. Favipiravir was prescribed only in severe cases. Other drugs commonly used is given in Table 2.

Table 2. Frequency of class of drugs prescribed and severity of illness.

DRUG CLASS	DRUG NAME	Mild N (%)	Moderate N (%)	Severe N (%)	Total (%)
Vitamins and minerals	Tab Vitamin C	154(54.23%)	109(38.38)	21(7.39)	284(94.74)
	Tab Vitamin A,D,E	150(56.82)	99(37.5)	15(5.68)	264(87.89)
	Tab. Zinc	150(66.08)	70(30.84)	7(3.08)	227(75.79)
Drugs acting on Gastrointestinal system	Inj. Pantoprazole	101(43.72)	109(47.19)	21(9.09)	231(76.84)
	Inj. Ondansetron	108(47.16)	100(43.67)	21(9.17)	229(76.32)
Antibiotics	Tab. Doxycycline	100(59.17)	63(37.28)	6(3.55)	169(56.32)
	Inj. Ceftriaxone	90(56.96)	53(33.54)	15(9.49)	158(52.63)
	Tab. Cefixime	20(40)	30(60)	0(0)	50(16.67)
	Tab. Amoxicillin+ Clavulanic acid	40(83.33)	8(16.67)	0(0)	48(16)
	Inj. Piperacillin+Tazobactam	0(0)	13(29.55)	31(70.45)	44(14.74)
	Tab. Norfloxacin	7(100)	0(0)	0(0)	07(2.33)
Antivirals	Inj. Remdesivir	80(49.08)	56(34.36)	27(16.56)	163(54.21)
	Tab. Favipiravir	0(0)	8(22.86)	27(77.14)	35(11.58)
	Inj. Casirivimab & Indiviimab	0(0)	0(0)	6(100)	6(2.10)
Drugs acting on heart and blood vessels	Inj. Dalteparin	103(46.82)	90(40.90)	27(12.27)	220(73.16)
	Tab. Aspirin	70(61.40)	40(35.09)	4(3.51)	114(37.90)
	Tab. Perfenidone	50(56.82)	38(43.18)	0(0)	88(29.47)
	Tab. Atorvastatin	23(69.70)	10(30.30)	0(0)	33(11.05)
	Tab. Amlodipine	20(74.07)	7(25.93)	0(0)	27(8.95)
	Tab. Clopidogrel	4(21.05)	5(26.32)	10(52.63)	19(6.32)
Antipyretics and anti-inflammatory	Tab. Paracetamol	150(52.45)	109(38.11)	27(9.44)	286(95.26)
Drugs acting on endocrine system	Inj. Methylprednisolone	75(35.55)	109(51.66)	27(12.80)	211(70.33)
	Inj. Dexamethaosne	60(60)	30(30)	10(10)	100 (33.33)
	Inj. Insulin	25(55.56)	20(44.44)	0(0)	45(15.26)
Antifungals/ Antiprotozoals	Tab. Ivermectin	15(71.43)	6(28.57)	0(0)	21(6.84)
	Inj. Amphotericin B	0(0)	5(45.45)	6(54.55)	11(3.68)
	Tab. Fluconazole	0(0)	3(100)	0(0)	3(1.05)
	Tab. Posaconazole	0(0)	0(0)	2(100)	2(0.52)
Drugs acting on Central Nervous System	Inj. Fosphenytoin	5(100)	0(0)	0(0)	5(0.13)
Drugs acting on Respiratory system	Tab. Aminophylline	6(100)	0(0)	0(0)	6(0.13)
Total		**1606(51.70)**	**1190(38.31)**	**310(9.99)**	**3106**

The minimum and maximum number of drug prescribed to single patient was 3 and 24 respectively .The average number of drugs per prescription was 11±5.1 SD.

Table 3. Frequency of drug prescribed per prescription.

Number of drugs per prescription	Number of prescriptions	Percentage of prescriptions
3-5	47	15.67
6-8	75	25
11-13	86	28.7
14-16	88	29.30
22-24	4	1.33
Total	**300**	**100**

The utilization of drug in COVID-19 wards were assessed through WHO core drug use prescribing indicators and around 1108 (35.7%) were found to be prescribed by generic name. The total number of injectable used was 1424 (45.8%). Majority of drugs i.e. 2262(72.8%) were prescribed from WHO essential drug list. Only a few fixed dose combination i.e. 92 (2.9%) were used.

Table 4. Drugs prescribed as per WHO core drug use indicators-prescribing indicators.

WHO core drug use indicators	Number (percentage)
Drugs prescribed by generic name (%)	1108(35.68)
Encounters with injections prescribed (%)	1424(45.83).
Prescribed drugs featuring in WHO essential drug list (%)	2262(72.81).
Drugs prescribed as FDC	92(2.96).

Discussion

The COVID-19 pandemic has imposed great challenges on healthcare systems worldwide. Some literature has been published on the clinical aspects of, possible treatments for and risk factors in patients with COVID-19.

Nevertheless, apart from a few studies, the epidemiology of and drug use profiles in patients with COVID-19 during the second wave has not been studied. Hence to further broaden our knowledge of drug utilization in the second wave of COVID-19, this study was conducted.

In our drug utilization study we analysed 300 prescriptions of COVID-19 positive patients. The prescriptions were diverse in practice, and most of the medications were prescribed considering the patient's characteristics, including disease severity, age and comorbidities.

In our study we found that the age group belonging to 41-50 years (19.7%) were slightly more affected than other age groups followed by 51-60 years (18.7%). Kumar et al., also has reported similar age preponderance in his study (3).

We also found that males (63.3%) were affected more than females (3.7%) in our study and this may again be due to more mobility of male population compared to female. This may be due to sex based immunological, genetic and life style difference like smoking amongst male population. Various studies have postulated the relation between COVID-19 infection and immunological, genetic and life style factors in males (18).

Around 45.8%, had associated comorbidities. Diabetes was the most common comorbidity which was seen in 15.3% patients followed by hypertension (12.6%) and Ischemic heart disease (5.3%). Similar results were found in the study conducted by Adekunle et al., (19).

A total of 3106 drugs were prescribed to the 300 patients. Polypharmacy was seen in all the prescriptions. The average number of drugs prescribed was 11±5.1. Since the treatment protocol of COVID-19 was not definite hence, polypharmacy may be justified in these study. Also the associated comorbidities in the patient further lead to polypharmacy.

Nearly all patients in this study received antibacterial, 68% received antivirals. However the most frequent prescription was that of analgesic and antipyretic drug paracetamol

(95.3%) followed by vitamin C and multivitamins which were prescribed to 94.7% and 87.9% patients respectively. This is in contrast to the study conducted by Madhav et al., where the most common prescription was that drug prescribed was Vitamin C followed by multivitamins (20).

Antibacterial were used in all the 300 cases and in some patient more than one antibiotic were prescribed. Doxycycline, was widely used during the first wave and early months of second wave due to its immunomodulatory, anti-inflammatory, cardioprotective and antiviral effects in patients with mild, moderate and severe disease. However we found that the use of Doxycycline gradually declined owing to change in treatment guidelines of WHO (21).

Other antibacterials commonly used were cephalosporins, amoxicillin- clavulanic acid combination and pipercillin –tazobactam combination. Our findings were different than the findings of Molla et al., where third generation cephalosporins and meopenam were the most commonly prescribed drugs (22).

Antiviral drug remdesivir was also used extensively in our study (54.2%). However use of remdesivir was reserved mainly for patients who were at high risk of progression to severe COVID-19, including hospitalization or death.

Other class of drugs which were commonly prescribed to more patients were dalteparin (73.2%) and corticosteroids like methyl prednisolone (52.6%) and dexamethasone (51.05%).

COVID-19 was associated with inflammation and hypercoagulable states and in some studies elevation of coagulation markers were associated with worse clinical outcomes. Many studies have shown decrease incidence of COVID-19, complications after initiation of anticoagulant therapy. Hence a large prescription of anticoagulants which were seen in our study was justified (23).

In our study we also found that corticosteroids were used in many patients and maximum patients received both methylprednisolone and dexamethasone. Many studies have concluded that methylprednisolone is better than dexamethasone as methyl prednisolone has better lung penetration than dexamethasone and overall mortality in patient receiving methylprednisolone was lower than those receiving dexamethasone. But in our study both were used simultaneously in maximum number of patients (24).

We also found that only 35.7% of the drugs were prescribed with generic name but since all the drugs were provided from hospital pharmacy the burden on patient regarding generic prescription was not there. 45.4% of the drugs were injectables. Since COVID-19 disease itself demands extensive and emergency treatments hence the higher percentage of injectable use in our study is justified.

Only 2.9% of the drugs were prescribed as fixed dose combinations. Hence in our study we did not find any inappropriate use of drug combinations.

In this study we included only the COVID-19 positive cases and not the suspected cases. Since suspected cases with COVID-19 like symptoms, and patient with positive contact history to COVID 19 patient were also given medication prophylactically they also added to the burden of drug utilization. As our study was a cross sectional study we did not monitor the progress of disease and their drug utilization in later course of disease. Also, considering the humongous nature of the outbreak analysis of only 300 samples will not adequately reveal the true nature of drug utilization.

In summary, the drug utilization for hospitalized patients with COVID-19 was diverse but generally complied with the ongoing guidelines. Polypharmacy was seen in our study and the average number of drug prescribed was large i.e. 11± 5.1.The associated comorbidities which was seen in 45.79% patients further added to polypharmacy. Despite polypharmacy the drug prescribed were mostly from the WHO essential drug list and percentage of fixed dose combination prescription was low. However not prescribing the drugs by generic name and large encounters of injectables was matter of concern. Still all the mentioned factors seems to be justifiable considering the aggressive and novel nature of the virus. But to get a better glimpse of drug utilization a more extensive study needs to be undertaken.

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