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DRUG UTILIZATION PATTERN AND DISEASE PROGRESSION IN HOSPITALIZED PATIENTS WITH COVID-19

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ABSTRACT: Background: The WHO declared the coronavirus disease 2019 (COVID-19) outbreak as a global pandemic in March 2020. Since, no specific drugs are currently available for its treatment it is important to document the prescription patterns. **Objectives:** To evaluate the drug prescribing pattern and assess the disease progression in the patients hospitalized with COVID-19 in a tertiary care hospital. **Methods:** It is a retrospective study. Using electronic hospital database, we identified 2302 patients between May 2021 to August 2021. Analysis was done using Microsoft Excel 2007. **Results:** Out of 2302 patients, 1406 (61.1%) were males and 896 (38.9%) were females. Majority were severe 1001 (43.5 %) followed by mild 664 (28.84 %), moderate 555 (24.1%) and asymptomatic 82 (3.56 %). Majority occurred 853 (37.1%) between51-70 years with slight male preponderance 558 (39.69%). Common co-morbidities were hypertension 666 (28.93%) and diabetes mellitus 482 (20.94 %). Total drugs prescribed were 6,123. Average number of drugs per prescription was 2.66. Corticosteroids 1560 (67.77%) and oxygen 1556 (67.59%) were most commonly prescribed. Piperacillin/Tazobactam was the most commonly prescribed antibiotic 1,153 (50.09%). Injectables used were 4,567 (198.4%). Generic drug prescription was 100%. Most drugs 5,515 (90.1%) were prescribed from NLEM, India, 2015. Inpatient mortality was 241 (10.47%), were predominantly male 190 (13.51%) and severe 167 (16.68%). 1896 (82.36%) were discharged and 165 (7.17%) remained hospitalized. **Conclusion:** Drug utilization for hospitalized patients with COVID-19 complied with the existing guidelines. Men with severe COVID-19 disease are more at risk for worse outcomes and death.

INTRODUCTION: A novel coronavirus, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged in December 2019 in Wuhan, the capital of Hubei province in China.

The virus is responsible for coronavirus disease (COVID-19), a disease ranging from a mild respiratory illness to a serious condition that can cause considerable mortality [1]. The second wave had a rapid course which started in the month of March-April 2021, and over the next 1-2 months, there was a sharp rise of cases and related deaths [2]. Cough without expectoration, scratchiness in throat, fever, reduced sense of smell and taste, difficulty in breathing, rhinorrhoea, myalgia, and change in bowel habits are common symptoms of COVID-19. However, immune-comprised person,

old age persons manifest severe COVID-19 illness and mortality. Diabetes, hypertension, malignancies, or renal disease were found more common among many of the severe COVID19 patients [3].

A wide range of repurposed drugs are being used to treat hospitalized COVID-19 patients. The COVID-19 pandemic has prompted healthcare providers to offer treatments that were suggested but not rigorously proven to be efficacious. Therefore, prescription patterns and sale of off-label medications have varied throughout the pandemic as hypotheses were being tested, myths being clarified, and new evidence continually emerged[4]. However, the research on wonder drugs for COVID-19 continues numbers of treatment guidelines using combinations of earlier used drugs are being tried by researchers around the world; their main is to reduce apprehension and mortality. However, as new research on COVID-19 pathogenesis and proofs on effectiveness of such treatments are being reported, there occur changes in these guidelines, leading to revised guidelines [3].

Effectiveness of such treatment guidelines can be assessed by understanding the prescribing patterns of drugs used in the treatment of COVID-19 patients. The data on drug utilization pattern and disease progression from this part of our country has not been done. Therefore, our present study aims to study the drug utilization pattern and disease progression in the patients with COVID-19 admitted in a tertiary care hospital.

MATERIALS AND METHODS:

Study Design: This is a retrospective study to evaluate the drug prescribing pattern and assess the disease progression in the patients hospitalized with COVID-19. Disease severity was assessed according to the guidelines of Clinical management protocol for COVID-19, Ministry of Health and family, Govt. of India (Version 6: May 24, 2021) [5], which are based on three levels of severity – mild, moderate and severe.

Study Period: Data for the last 4 months were collected for the period between 01 May 2021 to 30 August 2021 only after obtaining approval from the Institutional Ethical Committee (IEC) meeting. ECSMC Reference no. EC/SMC/2023/260.

Sample Size: A total of 2302 patient's medical record were analyzed on the basis of standard guidelines.

Inclusion Criteria: Patients of either sex, age $\geq$ 18 years, admitted to Silchar Medical College and Hospital, Silchar with laboratory-confirmed COVID-19 infection.

Exclusion Criteria:

➢ Patients < 18 years.

➢ Pregnant and lactating mothers.

Study Procedure: The study protocol was submitted to the Institutional ethical committee of Silchar Medical College and Hospital, Silchar, and approval was obtained before the commencement of the study. Data for the last 4 months were collected for the period between 01 May 2021 to 30 August 2021. Anonymity and confidentiality of the data were maintained throughout the study period and analysis.

Data Collection: The following data of patients admitted were collected from electronic hospital database of Silchar Medical College and Hospital, Silchar.

1. Demographic profile of the patients i.e name, age, gender, hospitalization date, co-morbidities.

2. The details of medication collected included the name of the prescribed drug, dosage form, daily dosage, frequency, duration of treatment and drugs prescribed by generic or brand name. Rationality of prescriptions was evaluated using the WHO core drug prescribing indicators.

3. Disease progression was assessing by prognosis (death, recovery or remained in hospital)

Data Analysis: Data were entered in computer database and statistical analysis was done with the help of Microsoft Excel 2007.

RESULTS: Table 1: shows that out of 2302 patients, 1406 (61.1%) were males and 896 (38.9%) were females. Mean age of the patients were 51 years. Out of 1406 males, 112 (7.97%) cases fall under the age group of 18 to 30 years,

508 (36.13%) under 31-50 years, 558 (39.69%) under 51-70 years and 228 (16.22%) were >70 years of age. Out of 896 (38.9%) females, 239 (26.67%) cases fall under the age group of 18 to 30 years, 264 (29.46%) under 31-50 years, 295 (32.92%) under 51-70 years and 98 (10.95%) were >70 years of age.

TABLE 1: DISTRIBUTION OF PATIENTS ACCRDING TO SEX AND AGE GROUP

Age in years	Total number of patients (n=2302)	Male (n=1406) (61.1%)	Female (n=896) (38.9%)
	n (%)	n (%)	n (%)
18-30	351 (15.3%)	112 (7.97%)	239 (26.67%)
31-50	772 (33.5%)	508 (36.13%)	264 (29.46%)
51-70	853 (37.1%)	558 (39.69%)	295 (32.92%)
>70	326 (14.1%)	228 (16.22%)	98 (10.95%)

Table 2 shows that among the 2302 patients majority of the patients were severe 1001 (43.5 %) followed by mild 664 (28.84%) moderate 555 (24.1%) and asymptomatic 82 (3.56 %). Out of 2302 patients 1485 (64.51%) had pre-existing co-morbidities. Most of the patients had hypertension 666 (28.93%) followed by diabetes mellitus 482 (20.94 %). Other associated co-morbidities are hypothyroidism 55 (2.39 %), cardiovascular diseases 46 (2 %), cardiovascular accident 45 (1.96%), chronic kidney disease 43 (1.87%), coronary artery disease 30 (1.3%), asthma 27 (1.17%), chronic liver disease 24 (1.04%), COPD 21 (0.91%), active tuberculosis 20 (0.87%), others 18 (0.78%), immunocompromised 8 (0.35%).

TABLE 2: DEMOGRAPHIC CHARACTERISTICS OF HOSPITALIZED COVID-19 PATIENTS BY DISEASE SEVERITY

Demographic characteristics	Total number of patients n=2302	Asymptomatic n=82 (3.56 %)	Mild n=664 (28.84 %)	Moderate n=555 (24.1%)	Severe n=1001 (43.5 %)
Gender		n (%)	n (%)	n (%)	n (%)
Male	1406 (61.1%)	15 (18.29%)	326 (49.1%)	370 (66.67%)	695 (69.43%)
Female	896 (38.9%)	67 (81.71%)	338 (50.9%)	185 (33.33%)	306 (30.57%)
Age (years)					
18-30	351 (15.3%)	54 (65.85%)	209 (31.48%)	37 (6.67%)	51 (5.09%)
31-50	772 (33.5%)	20 (24.39%)	249 (37.5%)	190 (34.23%)	313 (31.27%)
51-70	853 (37.1%)	8 (9.76%)	166 (25.0%)	231 (41.62%)	448 (44.76%)
>70	326 (14.1%)	0	40 (6.02%)	97 (17.48%)	189 (18.88%)
Co-morbidities			1485 (64.51%)		
Hypertension	666 (28.93%)	2 (2.44%)	97 (14.61%)	218 (39.28%)	349 (34.87%)
Diabetes Mellitus	482 (20.94%)	2 (2.44%)	71 (10.69%)	140 (25.23%)	269 (26.87%)
Hypothyroidism	55 (2.39%)	0	18 (2.71%)	10 (1.8%)	27 (2.7%)
Cardiovascular diseases	46 (2%)	0	8 (1.21%)	14 (2.52%)	24 (2.4%)
CVA	45 (1.96%)	1 (1.22%)	11 (1.66%)	13 (2.34%)	20 (2%)
CKD	43 (1.87%)	0	9 (1.36%)	11 (1.98%)	23 (2.3%)
CAD	30 (1.3%)	0	5 (0.75%)	12 (2.16%)	13 (1.3%)
Asthma	27 (1.17%)	0	5 (0.75%)	8 (1.44%)	14 (1.4%)
Chronic liver disease	24 (1.04%)	0	7 (1.05%)	8 (1.44%)	9 (0.9%)
COPD	21 (0.91%)	0	2 (0.3%)	6 (1.08%)	13 (1.3%)
Tuberculosis	20 (0.87%)	1 (1.22%)	5 (0.75%)	5 (0.9%)	9 (0.9%)
Others	18 (0.78%)	2 (2.44%)	9 (1.36%)	1 (0.18%)	6 (0.6%)
Immunocompromised	8 (0.35%)	1 (1.22%)	3 (0.45%)	3 (0.54%)	1 (0.1%)

Table 3 shows that a total of 6,123drugs were prescribed for 2302 COVID-19 patients. Remdesivir was not administered in asymptomatic patients, but was used in mild 22 (3.31%), moderate 150 (27.03%) and severe 436 (43.56%) patients. Enoxaparin was used in 2 (2.44%), 49 (7.38%), 193 (34.78%) and 446 (44.56%) patients presenting with asymptomatic, mild, moderate and severe symptoms respectively. Steroid was prescribed to 4 (4.88%), 152 (22.89%), 469 (84.51%) and 935 (93.41%) patients presenting with asymptomatic, mild, moderate and severe symptoms respectively. All the patients having moderate 555 (100%) and severe 1001 (100%)

symptoms were administered Oxygen. The most common antibiotics prescribed were Piperacillin+Tazobactam 1,153 (50.09%) followed by Ceftriaxone+Salbactam 467 (20.29%), Azithromycin 50 (2.17%) and Co-amoxiclav 39 (1.69%).

TABLE 3: PRESCRIPTIONSOF DRUGSIN PATIENTS HOSPITALIZED FOR COVID-19 BY DISEASE SEVERITY

Drugs	Total n =6,123	Asymptomatic n = 82	Mild n = 664	Moderate n = 555	Severe n = 1001
	n (%)	n (%)	n (%)	n (%)	n (%)
Remdesivir	608 (26.41%)	0	22 (3.31%)	150 (27.03%)	436 (43.56%)
Enoxaparin	690 (29.97%)	2 (2.44%)	49 (7.38%)	193 (34.78%)	446 (44.56%)
Oxygen	1556 (67.59%)	0	0	555 (100%)	1001 (100%)
Corticosteroids	1560 (67.77%)	4 (4.88%)	152 (22.89%)	469 (84.51%)	935 (93.41%)
Antibiotic					
Co-amoxiclav	39(1.69%)	9(10.98%)	30(4.52%)	0	0
Azithromycin	50(2.17%)	0	50(7.53%)	0	0
Ceftriaxone+Salbactam	467(20.29%)	0	170 (25.6%)	297(53.51%)	0
Piperacillin+Tazobactam	1,153(50.09%)	0	0	152 (27.39%)	1001 (100%)

Table 4 shows that out of 2302 prescriptions, the average number of drugs prescribed per prescription was 2.66. All the drugs 6,123 (100%) were prescribed by the generic names. Drugs prescribed from the National List of Essential Medicines of India (NLEM) were 5,515 (90.1%). Injectables were prescribed in 4,567 (198.4%) patients.

TABLE 4: THE WHO PRESCRIBING INDICATORS IN PATIENTS HOSPITALIZED FOR COVID-19

Indicators	
Total number of prescriptions analyzed	2,302
Total number of drugs prescribed	6,123
Average number of drugs per encounter	2.66
Percentage of encounters with an antibiotic	74.24%
Percentage of encounters with an injection	4,567 (198.4%)
Percentage of drugs prescribed from NLEM of 20155,515 (90.1%)	
Percentage of drugs prescribed by generic name	6,123(100%)

Table 5 shows that by August 2021, out of 2302 patients, 241 (10.47%) patients died and most of them were males 190 (13.51%) as compared to females 51 (5.69%). None of the patients died who were asymptomatic. Patients presenting with severe symptoms experienced higher percentage of death 167 (16.68%) compared to mild 15 (2.22%) and moderate 59 (10.63%) category. Out of 1896 (82.36%) discharged patients, 1074 (76.39%) were males and 822 (91.74%) were females. Highest percentage of discharge was seen in patients who were asymptomatic 80 (97.56%) compared to mild 598 (90.1%), moderate 458 (82.52%) and severe 760 (75.93%) cases. There were 165 (7.17%) patients who were still in the hospital. Most of them were males 142 (10.1%) as compared to females 23 (2.57%) and they were 2 (2.44%), 51 (7,68%), 38 (6.85%) and 74 (7.39%) in asymptomatic, mild, moderate and severe category patients respectively.

TABLE 5: HOSPITALIZATION OUTCOMES IN PATIENTS HOSPITALIZED FOR COVID-19 BY DISEASE SEVERITY

Hospitalization outcomes	Total number of patients n = 2302	Severity level on admission					
		Male n=1406	Female n = 896	Asymptomatic n = 82	Mild n = 664	Moderate n = 555	Severe n = 1001
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Inpatient mortality	241 (10.47%)	190 (13.51%)	51 (5.69%)	0	15 (2.22%)	59 (10.63%)	167 (16.68%)
Discharged from the hospital	1896 (82.36%)	1074 (76.39%)	822 (91.74%)	80 (97.56%)	598 (90.1%)	458 (82.52%)	760 (75.93%)
Remain in the hospital	165 (7.17%)	142 (10.1%)	23 (2.57%)	2 (2.44%)	51 (7.68%)	38 (6.85%)	74 (7.39%)

DISCUSSION: This study revealed that the prevalence of COVID-19 was more in males 1406 (61.1%) than females 896 (38.9%). A similar type of study done by Kushwaha S, showed that prevalence was more in males 73,797 (65.39%) than females 39,063 (34.61%) [6]. A study conducted by Bwire GM stated that the emerging gender gap may be due to possible factors such as higher expression of angiotensin-converting enzyme-2 (ACE 2; receptors for coronavirus) in male than female, sex-based immunological differences driven by sex hormone and X chromosome, gender behaviour (life style), such as far higher levels of smoking and drinking among men compared to women [7]. Our study showed that maximum number of cases occurred in the age group of 51-70 (37.1%) followed by 31- 50 (33.5%) in both the genders. Our findings are similar to a study conducted by Raj TH which showed that age group mostly affected was between the age group of 50 and 60 (42%) [8] whereas, another study by Tambe *et al.*, has reported that majority109 (55.4%) were between the age group of 31-60 years [9].

In our study, hypertension 666 (28.93%) and diabetes mellitus 482 (20.94 %) were the most common comorbidity. Similar results were found in other studies [10, 11, 12]. In patients suffering from hypertension, ACE-2 inhibitors, and angiotensin receptor blockers (ARBs) are frequently used for treatment. When used in a high amount, these inhibitors upregulate expression of the ACE-2 receptor, thereby leading to increased susceptibility to SARS-CoV-2 infection. People with diabetes are inclined to get infections due to impaired phagocytic cell capabilities [13].

Antiviral Remdesivir, off level drug, was prescribed in 608 (26.41%) of the patients. Its use was reserved for patients who were at higher risk of disease progression. Use increased from 22 (3.31%) in mild to 150 (27.03%) in moderate and 436 (43.56%) in severe patients. Presently as per ICMR guidelines, it is to be used under special circumstances for moderate to severe presentation who are on supplemental oxygen [14]. In the randomised, controlled ACTT-1 trials, patients in the remdesivir group were signifcantly more likely to have clinical improvements than those in the placebo group [11].

In our study, enoxaparin was used in 690 (29.97%) of the patients. Its use increased from 2 (2.44%) in asymptomatic to 446 (44.5%) in severe patients. A study done by Watanabe JH *et al.* showed that enoxaparin was used in >50% of the patients [15]. Vaughn VM *et al.*, suggested that prophylactic- and treatment-dose anticoagulation strategies are associated with lower in-hospital mortality[16].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 decreased incidence of COVID-19 complications after initiating anticoagulant therapy [17].

In the present study, most patients received corticosteroids 1560 (67.77%). There were similar findings in a study conducted by Best JH *et al*, where most common inpatient medications were corticosteroids 2055 (31.3%) [18]. Corticosteroids were used in 93.9% of the patients in a study done by Mustafa ZU*et al*, which was higher as compared to our study [19]. SARS-CoV-2 infection leads to an inflammatory response due to the release of various mediators like chemokines, cytokines, etc. and a dysregulated macrophage response also contributes to visceral inflammation. To control the inflammatory response, corticosteroids are being prescribed in the form inhalational budesonide for mild cases and systemic steroids are reserved for moderate to severe cases [14].

In our study we observed that oxygen was administered in all the patients who presented with moderate 555 (100%) and severe 1001 (100%) symptoms. Clinical management of moderate and severe cases should include oxygen support along with other symptomatic treatment [5]. Hypoxemia in COVID-19 ARDS occurs due to the presence of intrapulmonary ventilation perfusion mismatch or shunt. Such patients most benefit from oxygen delivery devices which may be invasive or noninvasive [20]. Aggressive oxygen therapy to correct hypoxia is critical for the successful treatment of COVID-19 patients and the reduction of mortality [21]. In the present study, the most common antibiotic used was piperacillin/ tazobactam 1,153 (50.09%). It was used at a higher rate in our study population as majority of the patients had severe symptoms and required oxygen

therapy. The findings are similar to the previous study conducted by Beovic B *et al*, who reported that in patients who were critically ill, piperacillin/ tazobactam were the most commonly prescribed antibiotic (50.3%) [22]. Another study conducted by Mohamad *et al,* showed that the most frequent antibiotics prescribed were amoxicillin/clavulanic acid (37.8%) [23] whose usage was low in our study 39(1.69%). Coronavirus Disease 2019 (COVID-19) is a viral disease thus untreatable by antibiotics, but the viral respiratory infections may clinically progress to bacterial pneumonia requiring antibiotic administration [12].

Various studies have also shown that most bacterial pneumonias that are diagnosed early in COVID-19 patients can be safely and effectively treated with antibiotics [24]. The superinfection of SARS-CoV-2 with other microorganisms, especially bacteria and fungi, is a determining factor in the evolution of COVID-19, increasing the difficulties in diagnosis, treatment, and prognosis. Bacterial superinfection in inpatients with COVID-19 relates to disease progression and prognosis [25].

We observed that an average number of drugs prescribed per prescription was 2.66 which is higher to WHO standard value, indicating the presence of polypharmacy [26]. Polypharmacy was also seen in other studies conducted by Manjhi *et al*, 27and and Tarai *et al*, [28]. 4,567 (74.59%) of the drugs were injectables. As the COVID-19 disease outbreak is due to novel SARS-CoV-2, it is necessary to treat the disease promptly to mitigate the severe and serious consequences of the pandemic. So, higher percentage of injectables were used. All the drugs (100%) were prescribed with generic name. The WHO proposes that all medicines (100%) should be prescribed optimally by generic names [26]. Drugs prescribe from the national list of essential medicines of India (NLEM), 2015 were 5,515 (90.1%) which is lower than the WHO standard value (100%) [26].

In the present study, total inpatient mortality was 241 (10.47%). Most of them were from severe category patients 167 (16.68%). Associated co-morbidity may be one of the reasons for severity and higher mortality. In another study by Goyal *et al* showed that mortality was seen predominantly in males and hypertension being the commonest co-

morbidity, but mortality rate of 22.8% was reported which is higher than our study [29]. The risk of death from COVID-19 strongly depends on age and previous health conditions. older patients and those with chronic comorbidities, such as cardiovascular disease, hypertension, diabetes, and pulmonary disease, are much more prone to critical and fatal disease outcomes [30]. Total 1896 (82.36%) patients were discharged from the hospital and most of the patients were from asymptomatic category 80 (97.56%). Patients who remained hospitalized in the without any ultimate hospital outcome (death and discharged alive) were 165 (7.17%).

CONCLUSION: Our study focused on drug utilization and disease progression of COVID-19 disease. The management of the patients complied with the existing recommendation issued by MoHFW & ICMR guidelines. The medications prescribed corelated with disease severity. Further studies are needed to be carried out extensively on larger sample size and longer duration of study to get the complete picture of the drug usage pattern and disease progression of COVID-19 disease from North-Eastern region of India.

Limitations of Our Study: The limitation of our study was that the sample size was relatively small, and the study period was short. We reported on only selected COVID-19 medications. Data on the use of other co-administered drugs for associated co-morbidities were not evaluated. Other determinants like laboratory parameters such as blood cell counts, inflammatory markers and radiology findings were not evaluated. Adverse events were not evaluated.

Strengths of Our Study: The study on drug utilization and disease progression in COVID-19 disease has not been done from the southern part of Assam. Our study was done in this region of Assam in a tertiary care hospital regarding the drug utilization and disease progression in COVID-19 patients and this study may serve as a guide to assess the medication use pattern from southern Assam. The present study may guide the researchers and physicians to better understand medicine use pattern and progression of the disease to improve the quality of healthcare delivery.

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