Case study

EVALUATION OF RECOVERY RATE IN COVID-19 PATIENTS TREATED WITH STEROIDAL DRUGS

ABSTRACT

Introduction: Coronavirus belongs to the family coronaviridae that majorly affects the respiratory system this group of virus outbreak previously as SARS and MERS in various countries and recently as COVID-19. COVID-19 has symptoms like fever, dry cough, breathing problems, loss of smell and taste, body aches. COVID-19 has spread to 210 countries and infected 272.51 million people worldwide, reached over 5.34 million deaths. Treatment includes antivirals, antibiotics, Non Steroidal Anti-Inflammatory Drugs, corticosteroids.

Methodology: It is a hospital-based retro-prospective study was conducted for 6 months in the Inpatient department. 100 patients were taken who met the inclusion criteria. Data collected and evaluated, analyzed by open label study.

Results and Discussion: severe COVID-19 can develop systemic inflammatory responses that can lead to lung injury and multisystem organ dysfunction. It has been proposed that the potent anti-inflammatory effects of corticosteroids might prevent or mitigate these deleterious effects. Both beneficial and deleterious clinical outcomes have been reported with the use of corticosteroids in patients with other pulmonary infections

From study, The Recovery% using steroids in the time period of 0-10 and 11-20 days was found to be 34 and 27% respectively. The Recovery percentage using steroids in the time period of 0-10 and 11-20 days was found to be 18 and 8% respectively. Dexamethasone was most commonly used in males and females, 77.08 and 84% respectively.

Conclusion: Considering beneficial effects of corticosteroids in COVID -19, prescribing steroids is safe by dose tapering continued up to 10days or hospital discharge

Keywords: COVID-19, Corticosteroids, Dexamethasone, Prednisolone

INTRODUCTION

Coronavirus is a large group of viruses belonging to the family coronaviridae that majorly affects the respiratory system. [1]

All the diseases caused by this virus are airborne which spread through the droplets of saliva. The outbreak of this virus dates back to Feb 2003 during which a disease named Severe acute respiratory syndrome (SARS) became an epidemic in China and other 4 countries.[2] Later in 2012, there was another disease outbreak named the Middle East

Respiratory Syndrome (MERS) was identified in Middle East, Africa, and South Asia. [3]

Recently in December 2019, a group of patients who live in the animal market got admitted to a local hospital in Wuhan with Pneumonia of unknown cause. By December 31, 2019, the Centre for disease control and prevention stated epidemiological investigation and took the sample of the patient and identified a virus belonging to genus beta coronavirus which is similar to SARS, and named it as 2019 –nCOV (covid-19) on January 30, 2020, WHO declared it as fast spreading virus due to increasing cases in China and other countries. [4]

The role of corticosteroids in treating severe infections has been an enduring controversy. [5-7] during the corona virus disease 2019 (COVID-19) pandemic, rigorous data on the efficacy of corticosteroids have been limited. [8, 9] The pandemic has been a potent stimulus for clinical research addressing this controversy.

As of July 24, 2020, 55 studies of corticosteroids for the treatment of COVID-19 have been registered on ClinicalTrials.gov. Recognizing the urgency of generating reliable data on the efficacy of corticosteroids to guide clinical management, the Clinical Characterization and Management Working Group of the World Health Organization (WHO) developed a protocol for a prospective meta-analysis[6] of ongoing randomized clinical trials.

While this initiative was in development, the United Kingdom based Randomized Evaluation of COVID-19 Therapy (RECOVERY) trial reported its findings from 6425 patients randomized to 6 mg/day of dexamethasone or usual care. Overall, dexamethasone resulted in an absolute reduction in mortality of 2.8% (22.9% vs 25.7% for usual care; age-adjusted rate ratio, 0.83 [95% CI, 0.75-0.93]). The benefit was greatest for patients who were receiving invasive mechanical ventilation at the time of randomization with mortality of 29.3% for dexamethasone vs 41.4% for usual care (rate ratio, 0.64 [95% CI, 0.51-0.81]) [7].

OBJECTIVES

- To analyze the various treatment options of covid-19.
- To determine the recovery rate of covid-19 using steroids.

METHODOLOGY

- **Study site:** Gandhi Hospital
- **Study design:** Prospective and Retrospective study design
- **Study duration:** Dec 2020 to May 2021.
- **Sample size:**100
- **Study approval:** Study protocol was approved by the Institutional Ethical Committee (IEC No: CMRCP/IEC/2020-21/ 004), CMR College of Pharmacy, Hyderabad.

INCLUSION CRITERIA:

Patients admitted with mild, moderate, severe COVID-19.

EXCLUSION CRITERIA:

Pediatrics below 5 years, Pregnancy and lactating women

RESULTS

The Total numbers of cases collected are 100.

N=100

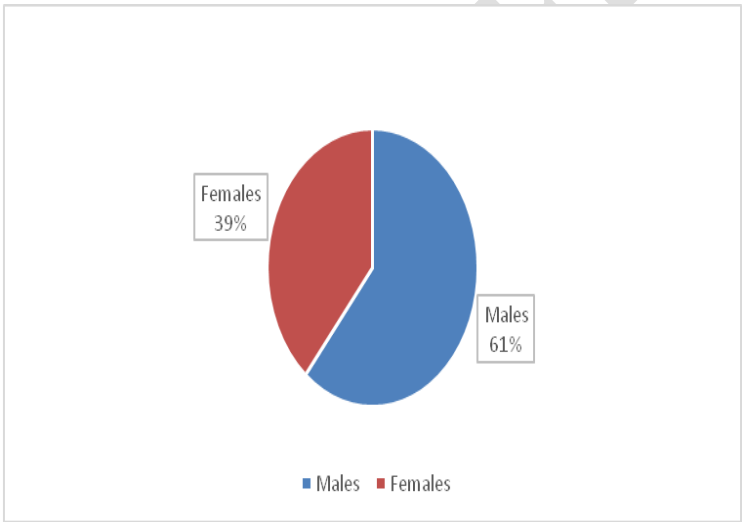

Fig. 1: Gender wise distribution

As per the demographic details of 100 In-patients obtained, 61 (61%) were male and 39 (39%) were female. Results were showed in **Fig. 1.**

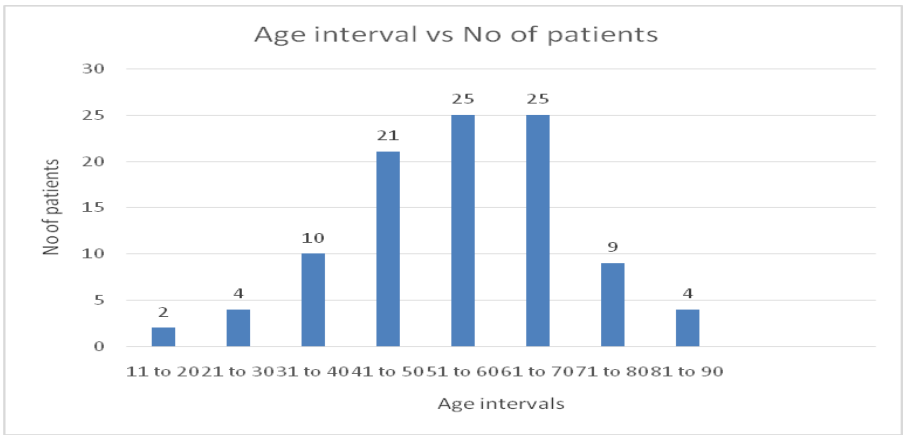

Fig. 2: Age-wise distribution

The age groups between 41-50 (21%), 51-60 (25%), and 61- 70(25%) are highly affected with covid 19. In both males and females the steroid usage Percentage was found to be 78% and female 64% respectively. Results were showed in **Fig. 2.**

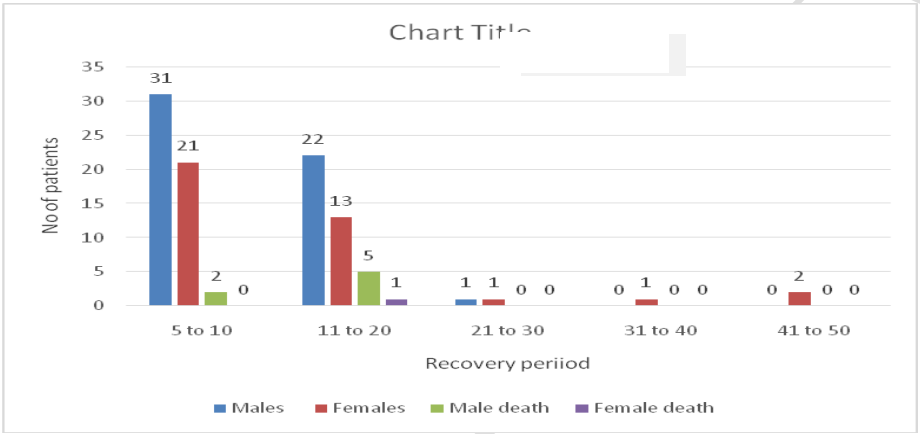

Fig. 3: Recovery Period

In both males and females the recovery period from covid 19 in 5-10days, was found to be 50.8% and females 53.84% respectively. Results were showed in **Fig. 3.**

Table 1: Recovery Period and Death % from time of Hospitalization in patients treated with steroids

Recovery period or Time of Hospitalization	Treated with Steroids	Percentage%	Treated with steroids (Death)	Percentage%
0-10	34	46.5	2	2.73
11-20	27	36.98	6	8.21
21-30	4	5.47	0	00
31-40	0	00	0	00
41-50	0	00	0	00
Total	65	88.8	8	10.94

Among 100 cases a total of 73 patients were treated with steroids in which 65 patients were recovered in 30days that is 88.8% of patients and 8 patients died that is 10.94% of patients. Results were showed in **Table 1.**

Table 2: Recovery Period and Death % in patients treated without steroids

Recovery period/ Treatment	Treated Without steroids	Percentage	Treated without steroids (Death)	Percentage
0-10	18	18	0	00
11-20	7	7	0	00
21-30	0	00	0	00
31-40	0	00	0	00
41-50	2	2	0	00
Total	27	27	0	00

Among 100 cases a total of 27 patients were treated without using steroids and all were recovered 50 days without any death cases. Results were showed in **Table 2.**

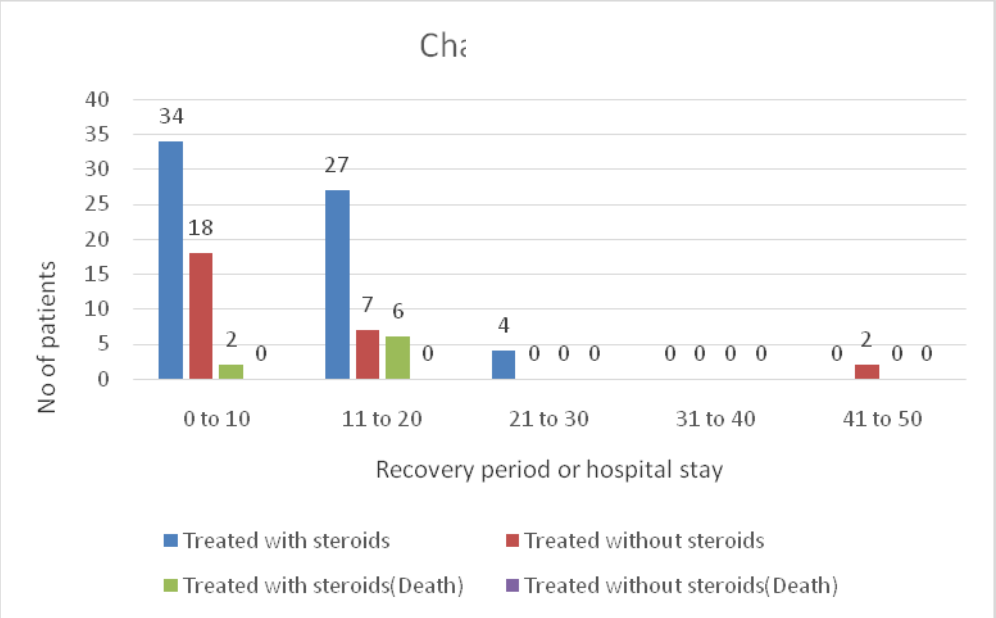

Fig. 4: Recovery Period in patients treated with and without steroids

The percentage of recovery in 0-10days and 11-20 days time period using steroids was found to be 34 and 27% respectively. The percentage of recovery in 0-10 days and 11-20 days time period without using steroid was found to be 18 and 8% respectively. Results were showed in **Fig. 4.**

Table 3: Steroids used in Covid 19 Patients

Gender	Dexamethasone	Percentage	Methyl Prednisolone	Percentage	Dexamethasone & Methyl Prednisolone	Percentage
Males	37	77.08	3	6.25	8	16.66
Females	21	84	2	8	2	8

Overall, 73 patients who were treated using steroids Dexamethasone was mostly used both in males and females. The Percentages were 77.08% respectively. Results were showed in **Table 3.**

Table 4: Treatment based on severity

No of patients	**Patients with O_2 supply**		**Patients without O_2 supply**	
	64		36	
No of patients	59	04	14	19
Percentage (%)	92.1	6.25	38.8	52.7

In 100 cases 64% of the patients were on O_2 supply and about 59 (92.1%) patients were treated using corticosteroids (Includes both Dexamethasone & Methyl Prednisolone). Results were showed in **Table 4.**

Discussion

Patients with severe COVID-19 can develop a systemic inflammatory response that can lead to lung injury and multisystem organ dysfunction. It has been proposed that the potent anti-inflammatory effects of corticosteroids might prevent or mitigate these deleterious effects. The Randomized Evaluation of COVID-19 Therapy (RECOVERY) trial, a multicenter, randomized, open-label trial in hospitalized patients with COVID-19, showed that the mortality from COVID-19 was lower among patients who were randomized to receive dexamethasone than among those who received the standard of care [10].

Both beneficial and deleterious clinical outcomes have been reported with the use of corticosteroids (mostly prednisone or methylprednisolone) in patients with other pulmonary infections. In patients with *Pneumocystis jirovecii* pneumonia and hypoxia, prednisone therapy reduced the risk of death; [11] however, in outbreaks of other novel coronavirus infections (i.e., Middle East respiratory syndrome [MERS] and severe acute respiratory syndrome [SARS]), corticosteroid therapy was associated with delayed virus clearance [12, 13]. In severe pneumonia caused by influenza viruses, corticosteroid therapy appears to result in worse clinical outcomes, including secondary bacterial infection and death. A total of 100 cases were collected and analyzed for the study.

From our study, it was observed that 61 (61%) were males and 39 (39%) were females. The age groups between 41-50 (21%), 51-60 (25%), and 61- 70(25%) are highly affected with covid 19 was observed.

In both males and females the steroid usage percentage was 78 and female 64% respectively. In both males and females the recovery period from covid 19 in 5-10days, was found to be 50.8% and females 53.84% respectively.

Among 100 cases a total of 73 patients were treated with steroids in which 65 patients were

recovered in 30days that is 88.8% of patients and 8 patients died that is 10.94% of patients. Among 100 cases a total of 27 patients were treated without using steroids and all were recovered in 50 days without any death cases.

The percentage of recovery in 0-10days and 11-20 days time period using steroids was found to be 46.5 and 36.98 % respectively. The percentage of recovery in 0-10 days and 11-20 days time period without using steroid was found to be 18 and 8% respectively

All the 73 patients who were treated with steroids, Dexamethasone most commonly used in both males and females. The Percentages were 77.08 and 84% respectively. The starting dose dosage of the Dexamethasone 8mg and then tapered to 6mg and 4 mg according to the severity.

Among the 100 cases 64% of the patients were on O_2 supply and about 59 (92.1%) patients were treated using corticosteroids.

CONCLUSION

In this study, the proportion of COVID 19 patients treated using corticosteroids was significantly higher than that of the patients treated without using steroids and the prescription of corticosteroids was found to be rational. Although there is no sufficient data to prove its benefits over risks, dosage tapering was seen for Dexamethasone where initially 8mg was prescribed and then tapered to 6mg and 4 mg. Considering the adverse and side effects of corticosteroids and also its beneficial effects against acute respiratory syndrome, dexamethasone was prescribed mostly in severe cases on ventilation and on O_2 support. Dexamethasone should be continued for up to 10days. However, further more studies are needed to validate the conclusive benefits of corticosteroids in COVID 19 patients.

Benefits of the study

- The optimal steroid to be used and the optimal timing of administration for which standard guidelines for the corticosteroids can be prepared.
- Further studies help to detect and monitor the drug interactions and drug utilization of corticosteroids.

REFERENCES

1. Pan zhai,Yanbing Ding, Yiming Li; The epidemiology diagnosis and treatment of COVID -19; International Journal of Antimicrobial Agents; 55(5): 105955; March28, 2020.
2. Lauren J Stockman, Richard Bellamy and Paul Garner; SARS; Systematic review of treatment effects; 3(9): e 343; sep12 ,2006
3. Thomas G. Ksiazek, Dean Erdman, Dr.P.H., CynthiaS. Goldsmith, M. S., SherifR. Zaki;

A Novel Corona Virus Associated with Severe Acute Respiratory Syndrome; The New England Journal of Medicine; 348: 1953-1966; May 15, 2003

4. Erika Cifuentes – Rodriguez; COVID-19: The outbreak caused by new coronavirus; Bol Med Hosp Infant Mex 77(2); 47-53; March 23, 2020.
5. Dale DC, Petersdorf RG. Corticosteroids and infectious diseases. *Med Clin North Am*. 1973; 57(5):1277-1287.
6. Annane D, Bellissant E, Bollaert PE, et al. Corticosteroids in the treatment of severe sepsis and septic shock in adults. *JAMA*. 2009; 301(22):2362-2375. Annane D, Bellissant E, Bollaert PE, et al. Corticosteroids for treating sepsis in children and adults. *Cochrane Database Syst Rev*. 2019; 12:CD002243.
7. Russell CD, Millar JE, Baillie JK. Clinical evidence does not support corticosteroid treatment for 2019-nCoV lung injury. *Lancet*. 2020; 395(10223):473-475.
8. Villar J, Confalonieri M, Pastores SM, Meduri GU. Rationale for prolonged corticosteroid treatment in the acute respiratory distress syndrome caused by coronavirus disease 2019. *Crit Care Explor*. 2020;2(4):e0111.
9. Recovery Collaborative Group, Horby P, Lim WS, et al. Dexamethasone in hospitalized patients with COVID-19 - preliminary report. *N Engl J Med*. 2020
10. Bozzette SA, Sattler FR, Chiu J, et al. A controlled trial of early adjunctive treatment with corticosteroids for Pneumocystis carinii pneumonia in the acquired immunodeficiency syndrome. California Collaborative Treatment Group. *N Engl J Med*. 1990;323(21):1451-1457
11. Arabi YM, Mandourah Y, Al-Hameed F, et al. Corticosteroid therapy for critically ill patients with Middle East Respiratory Syndrome. *Am J Respir Crit Care Med*. 2018; 197(6):757-767.
12. Stockman LJ, Bellamy R, Garner P. SARS: systematic review of treatment effects. *PLoS Med*. 2006;3(9): e343
13. Rodrigo C, Leonardi-Bee J, Nguyen-Van-Tam J, Lim WS. Corticosteroids as adjunctive therapy in the treatment of influenza. *Cochrane Database Syst Rev*. 2016;3: CD010406.