

Original Research Article

COMPARATIVE EFFICACY OF DEXAMETHASONE AND METHYLPREDNISOLONE IN MODERATE TO SEVERE COVID-19 PATIENTS – A RANDOMIZED CONTROLLED TRIAL.

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ABSTRACT

Objective: To compare the efficacy of Dexamethasone and Methylprednisolone in the treatment of moderate to severe COVID-19 patients.

Materials and Methods: A randomized controlled study was conducted over three months at Rajiv Gandhi Government General Hospital (RGGGH), Chennai. A total of 160 patients were enrolled, with follow-up data analyzed for 76 patients in the Dexamethasone group and 74 patients in the Methylprednisolone group. The primary outcome was all-cause mortality, and secondary outcomes included length of hospital stay. The Dexamethasone group received 8 mg IV daily, while the Methylprednisolone group received 80 mg IV twice daily, alongside standard care.

Results: There was no significant difference in mortality rates between the two groups. However, the Dexamethasone group exhibited shorter hospital stays (10.21 days vs. 15.09 days, p = 0.05) and faster symptom resolution. A significant reduction in inflammatory markers was observed in the Dexamethasone group, with higher CRP levels noted in the Methylprednisolone group (p < 0.001).

Conclusion: While mortality rates were comparable between the groups, Dexamethasone demonstrated superior outcomes in terms of shorter hospital stays and faster recovery, supported by a more favorable inflammatory profile. These findings suggest Dexamethasone may be a more efficient treatment option for moderate to severe COVID-19 patients.

Keywords: COVID-19, Clinical Improvement, Corticosteroids, Dexamethasone, Methylprednisolone, RT-PCR.

INTRODUCTION

The coronavirus disease 2019 (COVID-19), caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus, has become a global pandemic with significant health, social, and economic consequences. Since its emergence in December 2019, COVID-19 has led to millions of infections and deaths worldwide, putting unprecedented pressure on healthcare systems. The clinical spectrum of COVID-19 ranges from asymptomatic and mild cases to severe pneumonia, acute respiratory distress syndrome (ARDS), and multi-organ failure.^[1] Among the high-risk groups for severe disease are older adults and those with pre-existing comorbidities, such as hypertension, diabetes mellitus, cardiovascular disease, and chronic respiratory diseases.^[2] The pathophysiology

of severe COVID-19 involves an exaggerated immune response, often referred to as a "cytokine storm," which leads to widespread inflammation and organ damage.^[3] This excessive inflammatory response has led to the exploration of anti-inflammatory therapies, including corticosteroids, to modulate immune function and reduce morbidity and mortality.

Corticosteroids have been used in various inflammatory conditions, including ARDS, and have shown efficacy in reducing inflammation in COVID-19 patients with severe disease. In the context of COVID-19, corticosteroids like Dexamethasone and Methylprednisolone have treatment emerged as standard options. Dexamethasone, a potent synthetic glucocorticoid, was shown to reduce mortality in COVID-19 patients requiring supplemental oxygen in the trial.^[4] landmark RECOVERY This trial demonstrated that Dexamethasone reduced 28-day mortality by one-third in ventilated patients and by one-fifth in those receiving oxygen therapy, establishing its role as a cornerstone of COVID-19 management.^[4] Methylprednisolone, another corticosteroid, has been used in a variety of inflammatory conditions, including severe asthma, ARDS, and other forms of acute inflammation.^[5] It has also been used to treat COVID-19 patients with severe respiratory symptoms, although evidence comparing its efficacy to Dexamethasone remains limited.

Both Dexamethasone and Methylprednisolone exert their effects by modulating the immune response, particularly by suppressing the production of inflammatory cytokines and inhibiting the activation of immune cells such as T lymphocytes and macrophages. While Dexamethasone has been more extensively studied and endorsed in clinical guidelines for COVID-19 treatment. Methylprednisolone remains a common alternative due to its anti-inflammatory properties and longestablished use in severe inflammatory diseases. Despite the widespread use of both corticosteroids, the relative efficacy of Dexamethasone versus Methylprednisolone in the management of severe COVID-19 remains unclear, particularly regarding outcomes such as recovery time, inflammatory marker normalization, and all-cause mortality.

Several studies support the idea that corticosteroids are beneficial in COVID-19, particularly in patients with severe or critical illness. The RECOVERY trial4 and other clinical trials,^[6,7] have provided strong evidence for the use of Dexamethasone in improving survival outcomes in COVID-19 patients requiring oxygen.

On the other hand, the evidence for Methylprednisolone's efficacy in COVID-19 remains less conclusive. A study by Villar et al. (2020) suggested that methylprednisolone could benefit ARDS patients8, but direct comparisons with Dexamethasone have been scarce. In the present study, we aim to bridge this gap by directly comparing these two corticosteroids in the context of COVID-19.

The purpose of this study is to provide clinical evidence on which corticosteroid may offer the most effective treatment for moderate to severe COVID-19 in a real-world setting, specifically at a large teaching hospital in Chennai. We aim to assess whether Dexamethasone or Methylprednisolone should be considered the preferred therapy for these patients, or whether both treatments can be considered effective based on patient-specific factors.

MATERIALS AND METHODS

This was a prospective, open-label, randomized controlled trial conducted at Rajiv Gandhi Government General Hospital (RGGGH), Chennai, Tamil Nadu, over a period of 3 months. The study was approved by the institutional ethical committee (IEC-MMC-No.03042021), and informed consent was obtained from all participants. Study Population: A total of 245 patients were screened, out of which 160 patients were initially enrolled in the study, with 80 patients in each treatment group. However, during the study period, 4 patients from the Dexamethasone group and 6 patients from the Methylprednisolone group were lost to follow-up. As a result, the final analysis included 76 patients in the Dexamethasone group and 74 patients in the Methylprednisolone group. Inclusion Criteria: Patients aged 18-70 years, RTPCR positive for SARS-CoV-2, Moderate to severe disease (SpO2 <90.0% in room air). Written informed consent from the patient or legal guardian. Exclusion Criteria: Pregnancy or breastfeeding, patients already treated in other hospitals and referred here for further management Allergy to corticosteroids, already under steroid therapy for other diseases, Patients unwilling to participate in the study. Intervention: Patients were randomized into two treatment groups, Group 1 (Dexamethasone group): Received 8 mg IV daily for 10 days, along with standard care, Group 2 (Methylprednisolone group): Received 80 mg IV twice daily for 10 days, along with standard care. Outcome Measures: Primary Outcome: reduction of cause mortality. Secondary Outcomes: all Virological clearance (RT-PCR negative for SARSCoV-2), Return of inflammatory markers (CRP, ferritin) to baseline levels, length of hospital stay. Statistical Analysis: Data were analyzed using SPSS software. Continuous variables were analyzed using t-tests, and categorical variables were compared using Chisquare tests. The survival analysis were done using Kaplan Meyer test. A pvalue < 0.05 was considered statistically significant.

RESULTS

The present study compared the effectiveness of Dexamethasone (Dexa) and Methylprednisolone

(MPS) in the treatment of COVID-19 patients. A randomized controlled trial design was employed, and several variables were analyzed, including demographics, symptoms, comorbidities, laboratory findings, and treatment outcomes. There were no statistically significant differences in age or gender distribution between the two groups, indicating that the groups were comparable in these baseline characteristics. Both the Dexamethasone and Methylprednisolone groups had similar symptom onset times, with a comparable number of patients presenting symptoms within 1-5 days or more than 6 days of illness.

Regarding clinical symptoms, fever and cough were significantly more prevalent in the MPS group (fever: p = 0.029; cough: p = 0.001), indicating that patients in the Methylprednisolone group may have experienced more intense respiratory symptoms at the time of treatment initiation. However, other symptoms, including breathlessness, myalgia, headache, anosmia, and sore throat, did not show significant differences between the two groups.

Among the comorbid conditions reported, hypertension (HTN) and diabetes mellitus (DM) were significantly more common in the Dexamethasone group (p < 0.001 for HTN; p = 0.003 for DM). Other conditions such as coronary artery disease (CAD), chronic kidney disease (CKD), hypothyroidism, and cancer were equally distributed between the groups, with no significant differences observed.

The majority of patients in both groups were vaccinated (82.9% in the Dexa group vs. 81.1% in the MPS group), with no significant difference between the groups in terms of vaccination status. This highlights that the observed differences in outcomes were likely attributable to the corticosteroid treatment rather than differences in vaccination status.

C-reactive protein (CRP) levels, a marker of systemic inflammation, were significantly higher in the MPS group (p < 0.001), indicating a more pronounced inflammatory response in these patients. No significant differences were observed between the groups in terms of other laboratory parameters, such as D-dimer, white blood cell count (WBC), neutrophils, or lymphocytes. Treatment Outcomes, the hospital stay was significantly longer in the Methylprednisolone group (15.09 days vs. 10.21 days, p = 0.05), suggesting that patients in the Dexa group had quicker recoveries or required less intensive care. A higher proportion of MPS patients required extended hospital stays of more than 20 days, a difference that was statistically significant.

Mortality rates were higher in the MPS group (16.2%) compared to the Dexa group (7.9%), but the difference was not statistically significant (p = 0.094). This suggests that while mortality was numerically higher in the MPS group, the difference was not large enough to be considered clinically significant in this study's sample size.

The survival plot comparing cumulative survival rates between the Dexa and MPS groups revealed a notable difference in survival trends. The Dexa group (labeled as "0") showed a steeper decline in the survival curve early on, indicating quicker recovery or more immediate survival benefits. In contrast, the MPS group (labeled as "1") exhibited a slower but more prolonged decline, suggesting that patients in this group had a more gradual recovery trajectory. The Dexa group generally had shorter hospital stays, with cumulative survival reaching zero within approximately 20-30 days. The MPS group had a more extended hospital stay, with some patients remaining hospitalized for up to 120 days. The "plus" symbols on the survival plot indicate censored data (patients who were lost to followup or discharged before completing the study), and these were more prevalent in the MPS group. The logrank test for survival analysis showed a statistically significant difference in survival distributions between the two groups (p < 0.001), with the Dexa group exhibiting a survival advantage in terms of quicker recovery and shorter hospital stays.

Among the complications seen during the treatment period, the Mucormycosis was more prevalent in the MPS group (27.0% vs. 15.7% in Dexa). Other complications (readmissions, newly diagnosed diabetes, pneumothorax, DVT, and pulmonary embolism) did not significantly differ.

Overall, the Dexamethasone group demonstrated faster recovery, shorter hospital stays, and a more favorable inflammatory profile compared to the Methylprednisolone group. Although mortality was numerically higher in the MPS group, this difference was not statistically significant. The Methylprednisolone group showed prolonged hospital stays and more severe inflammation, as indicated by elevated CRP levels. These findings suggest that Dexamethasone may be more efficient in improving recovery times and reducing hospital burden in moderate to severe COVID-19 patients, although further studies are necessary to explore the clinical implications of these results, particularly concerning the severity of initial disease and the factors contributing to prolonged hospital stays in the MPS group.

Table 1: Baseline characteristics of the study population						
S. No	Variables	Category	Frequency	Percentage		
1	Age	19-45	45	30		
		46-60	54	36		
		>60	51	34		
2	Sex	Male	87	58		
		Female	63	42		

3	Onset of symptom	1-5 days	103	68.7
		>6 days	47	31.3
а	Fever	Yes	105	70
b	Cough	Yes	97	64.7
с	Breathlessness	Yes	79	52.7
d	Myalgia	Yes	34	22.7
e	Headache	Yes	21	14
f	Anosmia	Yes	12	8
g	Sore throat	Yes	30	20
4	Comorbidity			
а	CAD	Yes	20	13.3
b	HTN	Yes	25	16.7
с	DM	Yes	54	36
d	CKD	Yes	26	17.3
е	Hypo Thyroid	Yes	7	4.7
f	Cancer	Yes	4	2.7
g	Others	Yes	14	9.3
5	Vaccination status	Not vaccinated	123	82
		Single dose	9	6
		Two dose	18	12
6	SPO2	≥90	68	45.3
		<90	82	54.7
7	CRP	Mild <10	13	8.7
		Moderate 10-16	8	5.3
		Severe >16	129	86

Baseline characteristics of the study population, including age, sex, symptom onset, comorbidities, and vaccination status, distributed across both treatment groups.

S. No	Variables	Dexamethasone (n=76)	Methylprednisolone (n=74)	Significance
1	Age 19 -45	25 (55.6%) 32.9%	20 (44.4%) 27.0%	0.504
	46-60	24 (44.4%) 31.6%`	30 (55.6%) 40.5%	
	>60	27 (52.9%) 35.5%	24 (47.1%) 32.4%	
2	Male	45 (51.7%) 59.2%	42 (48.3%) 56.8%	0.445
	female	31 (49.2%) 40.8%	32 (50.8%) 43.2%	
3	Onset of symptom 1- 5 days	53 (51.55) 69.7%	50 (48.5%) 67.6%	0.456
	6-13 days	23 (48.9%) 30.3%	24 (51.1%) 32.4%	
4	Fever	59 (56.2%) 77.6%	46 (43.8%) 62.2%	0.029
5	Cough	59 (60.8%) 77.6%	38 (39.2%) 51.4%	0.001
6	Breathlessness	40 (50.6%) 52.6%	39 (49.4%) 52.7%	0.561
7	Myalgia	20 (58.8%) 26.3%	14 (41.2%) 18.9%	0.188
8	Headache	6 (28.6%) 7.9%	15 (71.4%) 20.3%	0.025
9	Anosmia	5 (41.7%) 6.6%	7 (58.3%) 9.5%	0.364
10	Sore throat	15 (50.0%) 19.7%	15 (50.0%) 20.3%	0.548
11	CAD	12 (60.0%) 15.8%	8 (40.0%) 10.8%	0.256
12	HTN	21 (84.0%) 27.6%	4 (16.0%) 5.4%	<.001
13	DM	36 (66.7%) 47.4%	18 (33.3%) 24.3%	0.003
14	CKD	8 (30.8%) 10.5%	18 (69.2%) 24.3%	0.021
15	Hypo Thyroid	3 (42.9%) 3.9%	4 (57.1%) 5.4%	0.485
16	Cancer	1 (25.0%) 1.3%	3 (75.0%) 4.1%	0.300
17	Others	7 (50.0%) 9.2%	7 (50.0%) 9.5%	0.589
18	Vaccination (No)	63 (51.2%) 82.9%	60 (48.8%) 81.1%	0.827
	1 st dose	5 (55.6%) 6.6%	4 (44.4%) 5.4%	
	2 nd dose	8 (44.4%) 10.5%	10 (55.6%) 13.5%	
19	CRP<10 mild	11 (84.65) 14.5%	2 (15.4%) 2.7%	0.010
	10-16 moderate	6 (75.0%) 7.9%	2 (25.0%) 2.7%	
	>16 severe	59 (45.7%) 77.6%	70 (54.3%) 94.6%	
20	D Dimer yes	9 (69.2%) 11.8%	4 (30.8%) 5.4%	0.133
	No	67 (48.9%) 88.2%	70 (51.1%) 94.6%	
21	WBC <11000	58 (50.9%) 76.3%	56 (49.1%) 75.7%	0.539
		18 (50.0%) 23.7%	18 (50.0%) 24.3%	
22	Neutrophil	0	1 (100%) 1.4%	0.493
		76 (51.0%) 100%	73 (49.0%) 98.6%	
23	Lymphocyte	8 (53.3%) 10.5%	7 (46.7%) 9.5%	0.522
	· ·	68 (50.4%) 89.5%	67 (49.6%) 90.5%	
24	Mortality status (Death)	6 (33.3%) 7.9%	12 (66.7%) 16.2%	0.094
	Discharged Alive	70 (53.0%) 92.1%	62 (47.0%) 83.8%	
25	Hospital stay 1-10days	66 (65.3%) 86.8%	35 (34.7%) 47.3%	< 0.001

Table 2: Comparison of demographic and clinical variables between the Dex	kamethasone and Methylprednisolone
groups	

11-15	5 (26.3%) 6.6%	14 (73.7%) 18.9%	
16-20	1 (10.0%) 1.3%	9 (90.0%) 12.2%	
21-29	2 (14.3%) 2.6%	12 (85.7%) 16.2%	
>30	2 (33.3%) 2.6%	4 (66.7%) 5.4%	

Comparison of demographic and clinical variables between the Dexamethasone and Methylprednisolone groups, highlighting statistically significant differences using chi Square p = <0.05 is statistically significant.

Table 3:	Table 3: Mean values of laboratory and clinical outcomes for the Dexamethasone and Methylprednisolone groups					
S. No	Variables	Dexamethasone	Methylprednisolone	Significance		
1	Age	54.8±14.16	53.36±13.92	0.75		
2	CRP	61.6±49.7	104.3±59.6	< 0.001		
3	Duration of the drug	5.62±3.42	6.11±2.9	0.34		
4	D-Dimer	2.6±2.2	3.2±5.9	0.408		
5	WBC	9.7±5.6	10.3±7.1	0.563		
6	Neutrophil	70.7±16.1	72.2±17.4	0.600		
7	Lymphocyte	16.8±12.2	15.6±11.3	0.558		
8	Number of days of hospital stay	10.21±16.3	15.09 ± 14.4	0.05		

Mean values of laboratory and clinical outcomes for the Dexamethasone and Methylprednisolone groups, including CRP levels, hospital stay duration, and other key parameters using independent t –test, p = <0.05 shows statistical significance.

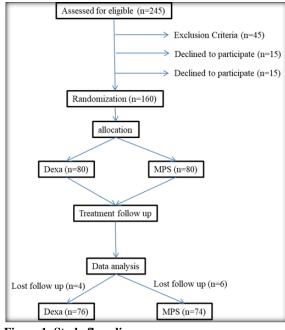
Table 4: Distribution of hospital stay duration among patients in the Dexamethasone and Methylprednisolone groups.

S. No	1-10 days	11-15 days	16-20	21-29	>1month
1	66 (86.8%)	5 (6.6%)	1 (1.3%)	2 (2.6%)	2 (2.6%)
2	35 (47.3%)	14 (18.9%)	9 (12.2%)	12 (16.2%)	4 (5.4%)

Table 5: Incidence of complications during treatment					
S. No	Variables	Dexa (n=76)	MPS (n=74)		
1	Readmission	4 (5.2%)	5 (6.7%)		
2	Newly diagnosed type I Diabetes mellitus	12 (15.7%)	14 (18.9%)		
3	Mucormycosis	12 (15.7%)	20 (27.02%)		
4	Pneumothorax	4 (5.2%)	2 (2.7%)		
5	DVT & Pulmonary Embolism	5 (6.5%)	3 (4.05%)		

Table 6: Outcome

Table 0. Outcome						
S. No	variables	Dexamethasone	Methylprednisolone	Significance		
1	Death	6 (7.9%)	12 (16.27%)	0.004		
2	Discharged alive	70 (92.1%)	62 (83.78%)	0.094		



Study Flow Diagram: Illustration of patient enrollment, randomization, follow-up, and analysis stages comparing the efficacy of Dexamethasone and Methylprednisolone in moderate to severe COVID-19 patients at RGGGH, Chennai.

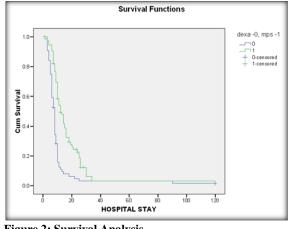


Figure 1: Study flow diagram

Figure 2: Survival Analysis

Treatment outcomes, including mortality rates and discharge status, comparing the efficacy of Dexamethasone and Methylprednisolone using Kaplan Meyer test.

DISCUSSIONS

The key finding of this study is that Dexamethasone treatment was associated with significantly shorter hospital stays and faster symptom resolution compared to Methylprednisolone, which aligns with findings from other large-scale studies. The trial.^[4] RECOVERY demonstrated that Dexamethasone reduced mortality by one-third in ventilated patients and by one-fifth in those receiving oxygen therapy, establishing it as a cornerstone treatment for COVID-19. Similarly, in this study, the Dexamethasone group experienced a shorter duration of hospitalization (10.21 days vs. 15.09 days, p = 0.05), a finding that underscores its potential to expedite recovery and reduce healthcare burden. Dexamethasone may offer advantages in terms of recovery speed and hospital resource utilization.

Methylprednisolone, while effective in reducing inflammation in conditions like ARDS, did not significant demonstrate advantages over Dexamethasone in terms of recovery time. The slightly higher mortality observed in the Methylprednisolone group (16.2% vs. 7.9%) may reflect more severe baseline characteristics or complications in this cohort, although this difference was not statistically significant (p = 0.094). These findings echo the results of earlier studies that suggest corticosteroids generally do not alter mortality outcomes dramatically, but their effects on recovery times and hospital resources can be more pronounced.^[6,7,10]

An important secondary outcome in this study was the return of inflammatory markers, particularly Creactive protein (CRP), to baseline levels. CRP levels were significantly higher in the MPS group (p 0.001), suggesting more severe ongoing < inflammation despite treatment. Elevated CRP is a well-documented marker of inflammation and poor outcomes in COVID-19 patients.^[3] The more rapid normalization of CRP in the Dexamethasone group may reflect better control of the hyper-inflammatory response associated with severe COVID-19 and cytokine storms. These results are consistent with findings from,^[9] Villar et al. (2020), who potential demonstrated the benefits of corticosteroids like Methylprednisolone in reducing inflammation in ARDS patients, but also pointed out that the optimal choice of corticosteroid might vary depending on individual patient responses.

The primary aim of the study was to assess the mortality as it remains a critical endpoint in the management of severe COVID-19. In this study, mortality rates were lower in the Dexamethasone group, although the difference did not reach

statistical significance. This finding aligns with the results of Horby et al. (2020), who reported reduced mortality in patients treated with Dexamethasone.^[4] While the study by Fadel et al. (2020) also suggested that corticosteroids reduce mortality in hospitalized COVID-19 patients, the absence of a significant mortality difference in this study could be due to other influencing factors such as baseline disease severity, coexisting medical conditions, or differences in clinical management.^[7]

Interestingly, the Dexamethasone group had a higher prevalence of comorbidities, such as hypertension and diabetes mellitus, conditions that are well-established risk factors for severe COVID-19 outcomes.^[2] Despite this, Dexamethasone treatment appeared to mitigate the effects of these comorbidities, allowing for quicker symptom resolution and hospital discharge. The ability of Dexamethasone to manage inflammation effectively might contribute to its superior recovery profile in this study population. This finding underscores the importance of considering both the medication and patient characteristics when assessing the efficacy of treatments for COVID-19.

These results suggest that Dexamethasone may be a more efficient corticosteroid option for managing moderate to severe COVID-19, particularly in terms of reducing hospital stays and promoting faster recovery. Given that a significant proportion of the global population remains susceptible to COVID-19, optimizing the use of corticosteroids is crucial for reducing healthcare resource utilization and improving patient outcomes. However, while Dexamethasone demonstrated a more favorable recovery profile, the study also highlights the importance of individualized treatment decisions. Factors such as disease severity, comorbidities, and the inflammatory response may influence treatment choice and outcomes. The findings of this study align with the broader literature, suggesting that Dexamethasone remains the preferred corticosteroid for COVID-19 treatment, but Methylprednisolone could still be considered for patients who do not tolerate Dexamethasone or require higher doses of corticosteroids.

Limitations of the study

This study has limitations. First, it was conducted at a single center, which may limit the generalizability of the findings to other populations or healthcare settings. Second, while the study used a randomized controlled trial design, the open-label nature of the trial could introduce bias in patient management and outcome assessment. Additionally, the relatively short follow-up period (3 months) does not provide insights into long-term outcomes such as post-acute sequelae of SARS-CoV-2 infection (PASC), commonly known as "long COVID."

CONCLUSION

In conclusion, this study provides evidence that Dexamethasone may offer superior clinical outcomes, including faster symptom resolution, shorter hospital stays, and more favorable inflammatory marker profiles, compared to Methylprednisolone in the treatment of moderate to severe COVID-19. While mortality rates did not differ significantly between the two groups, the differences in recovery profiles suggest that Dexamethasone may be the preferred corticosteroid for COVID-19 treatment, particularly in resourcelimited settings. However, additional research is necessary to further elucidate the reasons behind these findings and to validate these results across diverse populations.

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