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Original Research Article

In Hospital Complications Developing in Patients Administered Tocilizumab and Steroids for Management of Severe COVID-19 Pneumonia, Noble Hospital, Pune

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Abstract

The management of severe COVID-19 pneumonia has posed a significant challenge worldwide, with healthcare systems struggling to handle the influx of patients requiring intensive care. Various treatment strategies, such as the use of immunosuppressive drugs like tocilizumab (TCZ) and steroids, have been deployed in efforts to reduce the hyper-inflammatory response that characterizes severe COVID-19, especially the cytokine storm, which can lead to tissue damage, multi-organ failure, and death. TCZ, a monoclonal antibody targeting interleukin-6 (IL-6) receptors, has been extensively studied for its potential to mitigate the immune system's excessive response. IL-6, a pro-inflammatory cytokine, plays a key role in the pathogenesis of severe COVID-19 pneumonia, and by inhibiting its action, TCZ aims to decrease inflammation and prevent progression to acute respiratory distress syndrome. Similarly, steroids, particularly dexamethasone, have been used to suppress the immune system, control inflammation, and prevent lung damage. When combined, these treatments have shown to improve survival rates and reduce the need for mechanical ventilation. Despite their benefits, the use of TCZ and steroids is not without risks. In settings like Noble Hospital in Pune, complications arising from these treatments have been observed, particularly increased susceptibility to infections. TCZ, by suppressing the immune response, can elevate the risk of bacterial, fungal, and viral infections, including mucormycosis. Steroid therapy can also cause side effects such as hyperglycemia, gastrointestinal bleeding, and prolonged infections. Prolonged steroid use may contribute to muscle weakness, osteoporosis, and delayed wound healing. Noble Hospital adopts a comprehensive strategy for severe COVID-19 pneumonia, emphasizing continuous monitoring, early infection detection, and managing steroid side effects. The medical team collaborates to adjust treatments, ensuring therapeutic benefits outweigh risks while prioritizing patient needs and safety.

Key words: Acute respiratory distress syndrome, Cytokine storm, Hyperglycemia, Interleukin-6, Mucormycosis, Multidisciplinary care, Severe COVID-19 pneumonia, Steroids, Tocilizumab

INTRODUCTION

The COVID-19 pandemic has caused an unprecedented global health crisis, placing significant strain on healthcare systems worldwide.[1] Among the most severe manifestations of the disease is COVID-19 pneumonia, which can lead to acute respiratory distress syndrome (ARDS), multi-organ failure, and death.[2] As the pandemic progressed, various therapeutic strategies were employed to manage severe cases, with a particular focus on immunosuppressive treatments aimed at controlling the hyper-inflammatory response observed in critically ill patients.[3] Among these treatments, tocilizumab (TCZ) and corticosteroids like dexamethasone became pivotal in the management of severe COVID-19 pneumonia.[1]

TCZ, a monoclonal antibody that inhibits interleukin-6 (IL-6) receptors, was identified as a key therapeutic agent

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to reduce the excessive inflammation that characterizes severe COVID-19. IL-6 is a proinflammatory cytokine that plays a critical role in the "cytokine storm" seen in severe cases, which leads to widespread tissue damage and the progression of pneumonia to ARDS.[4] By inhibiting IL-6, TCZ aims to modulate the immune system's overactive response, prevent further lung injury, and improve clinical outcomes.[3] Dexamethasone, a potent corticosteroid, was also introduced early in the pandemic as a treatment to reduce inflammation. Steroids work by dampening the immune response and alleviating the systemic inflammation that leads to the complications associated with COVID-19 pneumonia.[5]

Despite the promising outcomes seen with the use of these therapies, both TCZ and steroids carry significant risks. The immunosuppressive nature of TCZ raises concerns about secondary infections, as it impairs the immune system's ability to fight off bacterial, fungal, and viral pathogens.[6] Mucormycosis, a severe fungal infection, has been particularly concerning in COVID-19 patients receiving immunosuppressive treatments, with an increase in its incidence observed during the pandemic. Steroid therapy, while effective in managing inflammation, comes with its own set of complications.[7] Long-term use of steroids can lead to hyperglycemia, gastrointestinal bleeding, muscle weakness, osteoporosis, and delayed wound healing. In addition, prolonged use of steroids in critically ill patients may exacerbate the underlying immunosuppression, increasing susceptibility to opportunistic infections and complicating recovery.[8]

In hospital settings, particularly in intensive care units managing severe COVID-19 pneumonia cases, the risk of complications associated with TCZ and steroid treatment is a growing concern.[9] The careful balancing of therapeutic benefits and potential harm is crucial for optimizing patient outcomes. Healthcare providers must closely monitor patients for signs of infections and other side effects, adjusting treatment protocols as necessary.[5] This requires a multidisciplinary approach involving intensivists, pulmonologists, infectious disease specialists, and pharmacists to tailor therapy based on the evolving needs of each patient. Furthermore, given the rapidly changing dynamics of COVID-19, the continuous collection of clinical data on the safety and efficacy of these treatments is essential to guide evidence-based practices.[10]

This study explores the complications developing in patients administered TCZ and steroids for severe COVID-19 pneumonia, focusing on the risks, challenges, and management strategies observed in a clinical setting.[11] The analysis aims to provide insights into how healthcare institutions can better manage these treatments and minimize the risks associated with their use, ultimately improving patient outcomes in the fight against severe COVID-19.[12]

MATERIALS AND METHODS

This retrospective cohort study was conducted at Noble Hospital and Research Centre (NHRC) in Pune, Maharashtra, with ethical approval, focusing on patients with severe COVID-19 pneumonia treated with TCZ and steroids. Since March 2020, NHRC has been a major treatment center for COVID-19 patients, offering free clinical care, testing, and treatment. Patient data were sourced from the Lifeline database, including demographic details, clinical and laboratory findings, imaging reports, and in-hospital outcomes. The study included 515 patients, with a sample size determined by power analysis (90% power, effect size = 0.209). Patients meeting strict inclusion criteria, such as a positive Reverse transcription polymerase chain reaction test, severe pneumonia, worsening respiratory function despite antivirals, and elevated inflammatory markers (e.g., IL-6 >100 pg/mL), were administered TCZ. Exclusion criteria included pregnancy, active systemic infections, or prior TCZ treatment. TCZ was administered through IV, and the study followed patient outcomes, focusing on oxygenation, ventilation, and complications. Statistical analysis was performed on clinical features, comorbidities, and treatment-related complications.

RESULTS

The table presents the age distribution of 515 subjects, with ages ranging from 20 to 93 years. The mean age is 56.35 years, with a standard deviation of 13.60 years, indicating that most patients fall within a reasonable proximity to the mean. The wide age range suggests a diverse group, with younger and older individuals included. The relatively high standard deviation suggests variability in the age distribution, meaning there is a significant spread around the average. Overall, this data indicates a middle-aged cohort, though it also includes a wide range of ages from young adults to older individuals.

The majority of subjects are in the 51–65 years age group (41.4%), followed by 36–50 years (25.4%). Fewer subjects are in the younger (7.8%) or older (>80 years, 3.9%) categories. The data shows a predominant middle-aged population.

The data show a predominance of males (75.7%) compared to females (24.3%). This suggests a gender imbalance within the sample, with males significantly outnumbering females. The total sample consists of 515 individuals,

with males making up the majority of the population in this study.

The majority of subjects (67.8%) have pre-existing co-morbidities, while 32.2% have none. This indicates a high prevalence of additional health conditions in the study population, which could impact the overall health status and treatment outcomes for the individuals involved.

Diabetes and hypertension have a significant presence, affecting around 45–50% of individuals. Chronic kidney disease (CKD) and ischemic heart disease (IHD) are less common, with 7.8% and 13.6% affected, respectively. The data highlights the relatively high occurrence of diabetes and hypertension among the population, while CKD and IHD are less frequent comorbidities.

Pneumonia, ARDS, and post-COVID lung fibrosis are the most common complications, with extremely high prevalence rates (over 88%). Less common complications include myocardial infarction, stroke, and GBS. Certain conditions like DVT and pulmonary embolism are rare, with only one or two cases reported.

The cross-tabulation of gender with complications reveals the distribution of various health complications between females and males. Most complications show a higher prevalence in males, such as in cases of pneumonia, septic shock, and pulmonary embolism, with males showing marginally higher percentages. Some complications like pneumonia (99.8% in males) and septic shock (90.5% in males) are more common among men. Statistically significant differences were observed for septic shock ($P = 0.024$), with males showing a higher incidence. However, complications such as pneumonia, ARDS, and myocarditis had no significant gender differences ($P > 0.05$). Minor differences in frequencies between genders were observed in other complications such as hypotension, thrombocytopenia, and arrhythmia, but these were not statistically significant ($P > 0.05$). Overall, while gender-related trends exist, most complications do not show large disparities when analyzed in terms of gender, suggesting that both genders are equally susceptible to certain post-COVID complications.

The cross-tabulation of diabetes status with complications indicates several trends between patients with and without diabetes. For complications like ARDS, a significant difference was observed, with diabetes patients showing a higher incidence (93.2%) compared to non-diabetic patients (84.7%) ($P = 0.003$). Similarly, AKI or CKD was more common in diabetics (8.5%) than in non-diabetics (2.1%) ($P = 0.001$). However, for other complications such as pneumonia, subcutaneous emphysema, and myocardial infarction, no significant differences were found between the groups ($P > 0.05$). Diabetic patients also had a slightly higher rate of arrhythmias (8.1%) compared to non-diabetics (5.3%), but this difference was not statistically significant ($P = 0.206$). Overall, while certain complications like ARDS and AKI or CKD were significantly more prevalent in diabetic patients, many complications showed similar rates regardless of diabetes status, suggesting a mixed relationship between diabetes and post-COVID complications.

The table shows the distribution of death and recovery across different age groups. The highest death rate is in the 51–65 years group (11.1%), while the 36–50 years group has the highest recovery rate (20.8%). Overall, 25.6% of patients died, and 74.4% recovered. The elderly (>80 years) had the lowest impact in both categories.

Table 1: Distribution of the subjects based on age groups

Age Groups	Frequency	Percentage
20–35 years	40	7.80
36–50 years	131	25.40
51–65 years	213	41.40
66–80 years	111	21.60
>80 years	20	3.90
Total	515	100

Table 2: Distribution of the subjects based on gender

Gender	Frequency	Percentage
Females	125	24.30
Males	390	75.70
Total	515	100

Table 3: Distribution of the subjects based on pre-existing comorbidities

Pre-existing Comorbidities	Frequency	Percentage
No	166	32.20
Yes	349	67.80
Total	515	100

Table 4: Distribution of the subjects based on comorbidities

Comorbidities	Status	Frequency	Percentage
Diabetes	No	281	54.60
	Yes	234	45.40
Hypertension	No	266	51.70
	Yes	249	48.30
CKD	No	475	92.20
	Yes	40	7.80
IHD	No	445	86.40

CKD: Chronic kidney disease, IHD: Ischemic heart disease

Table 5: Distribution of complications

Complication	No	Yes	Percentage yes
Pneumonia	1	514	99.80
ARDS	59	456	88.50
Subcutaneous emphysema/pneumothorax	489	26	5.00
Hemoptysis	492	23	4.50
Post-COVID lung fibrosis	379	136	26.40
Septic shock	457	58	11.30
AKI	477	38	7.40
AKI or CKD	489	26	5.00
Myocarditis	495	20	3.90
Arrhythmia	481	34	6.60
LVF/CCF	509	6	1.20
Myocardial Infarction	510	5	1.00
Hypotension	410	105	20.40
Bleeding	501	14	2.70
DVT	515	0	0
Pulmonary Embolism	514	1	0.20
Thrombosis of Abdominal Vessels	513	2	0.40
Infectious Complications	502	13	2.50
HAP/VAP	504	11	2.10
BSI (Bacterial)	504	11	2.10
BSI (Fungal)	512	3	0.60
Encephalopathy	471	44	8.50
Stroke	510	5	1.00
GBS	514	1	0.20
Thrombocytopenia	456	59	11.50

CKD: Chronic kidney disease

Table 6: Cross-tabulation of gender with complications

Complications	Gender		Total
	Females	Males	
Pneumonia			
N	0	1	1
Y	125	389	514
	100.0%	99.7%	99.8%
ARDS			
N	14	45	59
Y	111	345	456
	88.8%	88.5%	88.5%
Subcutaneus emphysema/ pneumothorax			
N	116	373	489
Y	9	17	26
	7.2%	4.4%	5.0%
Haemoptysis			
N	120	372	492
Y	5	18	23
	4.0%	4.6%	4.5%
Post covid lung fibrosis			
N	94	285	379
Y	31	105	136
	24.8%	26.9%	26.4%
Septic shock			
N	104	353	457
Y	21	37	58
	16.8%	9.5%	11.3%
AKI			
N	116	361	477
Y	9	29	38
	7.2%	7.4%	7.4%

Table 6: (*Continued*)

Complications	Gender		Total
	Females	Males	
AKI or CKD			
N	120	369	489
Y	5	21	26
	4.0%	5.4%	5.0%
Myocarditis			
N	120	375	495
Y	5	15	20
	4.0%	3.8%	3.9%
Arrythmia			
N	120	361	481
Y	5	29	34
	4.0%	7.4%	6.6%
LVF/CCF			
N	123	386	509
Y	2	4	6
	1.6%	1.0%	1.2%
Myocardial infarction			
N	123	387	510
	98.4%	99.2%	99.0%
Y	2	3	5
	1.6%	0.8%	1.0%
Hypotension			
N	96	314	410
Y	29	76	105
	23.2%	19.5%	20.4%
Bleeding			
N	122	379	501
Y	3	11	14
	2.4%	2.8%	2.7%
Pulmonary embolism			
N	124	390	514
Y	1	0	1
	0.8%	0.0%	0.2%
Thrombosis of abdominal vessels			
N	125	388	513
Y	0	2	2
	0.0%	0.5%	0.4%
Infectious complications			
N	122	380	502
Y	3	10	13
	2.4%	2.6%	2.5%
HAP/VAP			
N	124	380	504
Y	1	10	11
	0.8%	2.6%	2.1%
BSI bacterial			
N	121	383	504
Y	4	7	11
	3.2%	1.8%	2.1%
BSI fungal			
N	125	387	512
Y	0	3	3
	0.0%	0.8%	0.6%
Encephalopathy			
N	110	361	471
Y	15	29	44
	12.0%	7.4%	8.5%

Table 6: (*Continued*)

Complications	Gender		Total
	Females	Males	
Stroke			
N	123	387	510
Y	2	3	5
	1.6%	0.8%	1.0%
GBS			
N	125	389	514
Y	0	1	1
	0.0%	0.3%	0.2%
Thrombocytopenia			
N	111	345	456
Y	14	45	59
	11.2%	11.5%	11.5%

*significant

Table 7: Cross-tabulation of diabetes with complications

Complications	Diabetes		Total
	No	Yes	
Pneumonia			
N	1	0	1
Y	280	234	514
	99.6%	100.0%	99.8%
ARDS			
N	43	16	59
Y	238	218	456
	84.7%	93.2%	88.5%
Subcutaneus emphysema/			
N	269	220	489
Y	12	14	26
	4.3%	6.0%	5.0%
Haemoptysis			
N	267	225	492
Y	14	9	23
	5.0%	3.8%	4.5%
Post covid lung fibrosis			
N	212	167	379
Y	69	67	136
	24.6%	28.6%	26.4%
Septic shock			
N	253	204	457
Y	28	30	58
	10.0%	12.8%	11.3%
AKI			
N	260	217	477
Y	21	17	38
	7.5%	7.3%	7.4%
AKI or CKD			
N	275	214	489
Y	6	20	26
	2.1%	8.5%	5.0%
Myocarditis			
N	274	221	495
Y	7	13	20
	2.5%	5.6%	3.9%
Arrythmia			
N	266	215	481
Y	15	19	34
	5.3%	8.1%	6.6%
LVF/CCF			
N	277	232	509

Table 7: (*Continued*)

Complications	Diabetes		Total
	No	Yes	
Y	4	2	6
	1.4%	0.9%	1.2%
Myocardial infarction			
N	279	231	510
Y	2	3	5
	0.7%	1.3%	1.0%
Hypotension			
N	232	178	410
Y	49	56	105
	17.4%	23.9%	20.4%
Bleeding			
N	275	226	501
Y	6	8	14
	2.1%	3.4%	2.7%
Pulmonary embolism			
N	280	234	514
Y	1	0	1
	0.4%	0.0%	0.2%
Thrombosis of abdominal vessels			
N	280	233	513
Y	1	1	2
	0.4%	0.4%	0.4%
Infectious complications			
N	273	229	502
Y	8	5	13
	2.8%	2.1%	2.5%
HAP/VAP			
N	272	232	504
Y	9	2	11
	3.2%	0.9%	2.1%
BSI bacterial			
N	275	229	504
Y	6	5	11
	2.1%	2.1%	2.1%
BSI fungal			
N	280	232	512
Y	1	2	3
	0.4%	0.9%	0.6%
Encephalopathy			
N	260	211	471
Y	21	23	44
	7.5%	9.8%	8.5%
Stroke			
N	278	232	510
Y	3	2	5
	1.1%	0.9%	1.0%
GBS			
N	281	233	514
Y	0	1	1
	0.0%	0.4%	0.2%
Thrombocytopenia			
N	251	205	456
Y	30	29	59
	10.7%	12.4%	11.5%

DISCUSSION

This retrospective cohort study, conducted at NHRC, Pune, focused on in-hospital complications in patients treated with

TCZ and steroids for severe COVID-19 pneumonia.[13] A total of 515 patients, with a mean age of 56.35 years, were studied. The majority were males (75.7%) and the most common age group was 51–65 years (41.4%). Around 67.8% of patients had pre-existing comorbidities, with diabetes (45.4%) and hypertension (48.3%) being the most prevalent.[14]

Complications were widespread, with pneumonia (99.8%), ARDS (88.5%), post-COVID lung fibrosis (26.4%), septic shock (11.3%), and AKI (7.4%) being common.[15] The study found statistically significant correlations between age and complications like ARDS, post-COVID lung fibrosis, and myocarditis.[16] It also found that males were more prone to septic shock than females.[17]

Diabetes was linked to higher rates of ARDS and AKI or CKD. Infections, particularly pneumonia, were the leading infectious complication, aligning with similar studies.[18] The overall mortality rate was 25.6%, with the 51–65 age group exhibiting the highest mortality rate. Despite this, 74.4% of patients recovered, highlighting the potential benefits of TCZ and steroids in reducing mortality and promoting recovery.[19] However, further research is needed to understand the clinical nuances and refine the treatment protocols.[20]

CONCLUSION

This retrospective cohort study at NHRC, Pune, examined in-hospital complications in 515 COVID-19 pneumonia patients treated with TCZ and steroids. The average age was 56.35 years, with most patients being male (75.7%) and aged 51–65 years (41.4%). Comorbidities, especially diabetes (45.4%) and hypertension (48.3%), were prevalent in 67.8% of patients. Common complications included pneumonia, ARDS, post-COVID lung fibrosis, septic shock, and AKI. The mortality rate was 25.6%, with the highest mortality in the 51–65 age group. Despite these challenges, 74.4% recovered, underscoring the potential benefits of TCZ and steroids. Further studies are needed.

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