Study of Determination of Sex differences in the Susceptibility, Severity, and Outcomes of Coronavirus disease; A Prospective Observational Study at a tertiary care hospital at Durgapur

By

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Dissertation submitted in partial fulfilment of the requirements of the degree MBA Hospital and Health Management
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To Whom It May Concern

This is to certify that **Dr. Srujana Janga** has done her three months dissertation on "Study on determination of sex differences with respect to susceptibility, severity & outcomes of Corona Virus disease; A prospective observational study at The Mission Hospital, Durgapur" from 22.03.2021 to 21.06.2021.

During the period of dissertation she has been found sincere.

We wish her a successful future and career ahead.

Ramesh Lall
VP – HR

Dr. Partha Pal
Chief Medical Superintendent

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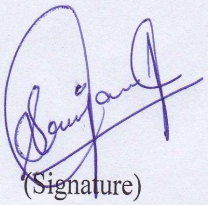
DECLARATION BY STUDENT

I hereby declare that this dissertation titled **"Study on determination of sex differences with respect to susceptibility, severity and outcomes of corona virus disease; A prospective observational study at a tertiary care hospital in Durgapur"** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



(Signature)

Dr. Srujana Janga

Date: 19/6/21

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I hope that I can build upon the experience and knowledge that I have gained and make a valuable contribution towards the industry in coming future.

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Abstract:

***Aim*:** To Determine the Effect of Sex differences in the Coronavirus disease.

***Objectives*:** To analyse the Susceptibility, Severity, and Outcomes of Coronavirus disease with respect to the gender differences. To provide recommendations based on study findings.

***Research problem*:** What is the Effect of Sex differences in the Susceptibility, Severity, and Outcomes of Coronavirus disease positive patients admitted into the hospital?

***Methodology*:** This study was conducted at The Mission Hospital, a 350-bed super-specialty hospital located in Durgapur, West Bengal, India, it was carried out for 3 months between April 6th and June 10th, 2021, analysing 84 COVID positive patients closely under medical supervision with all ethical considerations and followed by the COVID guidelines. Patients admitted into MIC, CCU, ICU were included and followed up. Specially designed data collection form was used to collect the patient's details which is later/parallelly been entered into the Electronic Medical Records. The data was analysed with the Microsoft EXCEL making Tabular plots and calculated percentage variations for specific data and comparative analysis was done.

***Key results*:** The total Mortality Rate / Death Rate identified in 3 months was 69.04%, of which male death rate was 48.8% and female death rate was 20.23%.

***Conclusion*:** The present study is an Evident that suggests to the local and global research that men are more prone to the COVID and are more vulnerable to the Susceptibility, Severity, and Outcomes of the Corona Virus Disease.

***Keywords*:** COVID Sex Differences, Sex Variations in COVID Immune Response, COVID Male vs Female.

List of Symbols and Abbreviations

COVID-19	Corona Virus Disease - 2019 novel coronavirus
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
USA	United States of America
MICU	Medical Intensive Care Unit
CCU	Corona Care Unit
ICU	Intensive Care Unit
EMR	Electronic Medical Records
HTN	Hypertension
DM	Diabetes Mellitus
CKD	Chronic Kidney Diseases
ICMR	Indian Council of Medical Research
WHO	World Health Organisation
CDC	Centre for Disease Control
ARF	Acute Renal Failure
MOD	Multiorgan Dysfunction
OD	Once Daily
BD	Twice Daily
TDS	Thrice Daily
STAT	Slow and controlled
P/O	Per Oral
SOS	Whenever Necessary
ODHS	Once Daily Hour of Sleep
TMPRSS2	Transmembrane protease serine 2

Chapter 1

Introduction:

As the Coronavirus Disease (COVID-19) continues to emerge and change worldwide, subordinate groups with higher levels of disease are identified. Separating the risk of coronavirus 2 infection (SARS-CoV-2) or the associated effects of COVID-19 is important in developing targeted prevention and control strategies[1]. Advanced age and current cardiovascular conditions have been reported to be associated with adverse effects. Gender is increasingly recognized as an important factor in epidemiology and because of many diseases. This appears to have caught coronavirus 2019 infection (COVID-19). Evidence from China and Europe has suggested that deaths from COVID-19 infections are higher in men than in women, but evidence from the US population is lacking[2].

Most countries with available data show a male-to-female mortality rate of more than 1.0, reaching 3.5 in some cases. However, the mortality rate of COVID-19 cases is higher for women than for men in a few countries, such as India, which is one of the country's most affected[3]. As of September 30, 2020, India had more than 6.4 million recorded cases of COVID-19 cases. In India, the mortality rate for COVID-19 cases among men is 2.9% and 3.3% for women. The death toll in Nepal, Vietnam, and Slovenia is also much higher for women than men. These findings are surprising because global data have shown that both biological factors (strong immune responses) and risk behaviours (e.g., such discriminatory findings on intercourse and COVID-19 mortality between countries may reflect incomplete COVID-19 data in them)[4]. All geographies, discrimination in the case of sexual identification, or high risks for women in certain countries due to human characteristics or health profiles of countries[5]. In India, the mortality rate of COVID-19 cases is lower than that seen in high-

income countries, such as the USA. is the age-old structure of the Indian people, with more young people than the people of US[6].

A consistent feature of the ongoing coronavirus disease 2019 (COVID-19), caused by the acute novel acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is discriminatory against men in dealing with serious illnesses[7]. Apart from this, there are a few reviews that look at whether this is a global cause and not a regional one. There are limited data showing that bias and an increase in male mortality are due to an increase in male infections, or a true representation of more serious diseases. This gap in the literature underscores the fact that sex remains a serious matter when researching the effects of infectious diseases. In addition, much of this difference in the number of deaths is due to sexual behaviour (lifestyle), that is, higher smoking and drinking rates among men compared to women[8]. Finally, research reported that women were more likely to respond to the Covid-19 epidemic than men. The reckless attitude among men undermines their ability to take preventive measures, such as washing their hands regularly, wearing a face mask, and staying on top of household orders[9].

***Aim*:** To Determine the Effect of Sex differences in the Coronavirus disease.

Objectives:

1. To analyse the Susceptibility, Severity, and Outcomes of Coronavirus disease with respect to the gender differences.
2. To provide recommendations based on study findings.

Chapter 2

Literature Review:

The literature review related to this research topic is summarized below:

Author (Year)	*Study location*	*Sample size*	*Salient features*
Boehmer TK, DeVies J, Caruso E, van Santen KL, Tang S, Black CL, et al (2020)	United States CDC COVID-19 Response Team; ICF International Inc., Atlanta, Georgia.	Population from 50 states in America	Increases in the percentage of positive SARS-CoV-2 test results among adults aged 20-39 years preceded increases among adults aged ≥60 years by an average of 8.7 days (range = 4-15 days), suggesting that younger adults likely contributed to community transmission of COVID-19.
Razzaghi H, Wang Y, Lu H, Marshall KE, Dowling NF, Paz-Bailey G, et al. (2020)	United States	437,500 persons	Median county prevalence of any of five underlying medical conditions that increase the risk for severe COVID-19–associated illness was 47.2%, and prevalences were higher in counties in the southeastern United States and in more rural counties

African Population and Health research centre The Sex, Gender and Covid-19 Project (2020)	COVID-19 Project The COVID-10 sex-disaggregated data tracker.	Global data processing	Differences in women's and men's bodies due to their sex is playing a role in people's risk of illness and death due to COVID 19.
Joe W, Kumar A, Rajpal S, Mishra US, Subramanian SV (2020)	COVID-19 cases in India publicly available for download at https://www.covid19india.org/.	Complete covid data online	Early evidence indicates that males have higher overall burden, but females have a higher relative-risk of COVID-19 mortality in India. Elderly males and females both display high mortality risk and require special care when infected.
Bwire GM (2020)	Tanzania	Review	large part of this difference in number of deaths is caused by gender behavior (lifestyle), i.e., higher levels of smoking and drinking among men compared to women
Griffith DM, Sharma G, Holliday CS, et al. (2020)	United States Centers for Disease Control and Prevention	COMMENTARY	Data suggest that more men than women are dying of coronavirus disease 2019 (COVID-19) worldwide, but it is unclear why
Scully, E. P., Haverfield, J., Ursin, R. L., Tannenbaum, C. & Klein, S. L.	Division of Infectious Diseases, Department	Nature Reviews Immunology	A male bias in mortality has emerged in the COVID-19 pandemic, which is consistent with the

(2020)	of Medicine, Johns Hopkins University, Baltimore, MD, USA		pathogenesis of other viral infections.
Richardson, S. et al. (2020)	New York city, USA	5700 from 12 hospitals in New York City	Among patients who were discharged or died (n = 2634), 14.2% were treated in the intensive care unit, 12.2% received invasive mechanical ventilation, 3.2% were treated with kidney replacement therapy, and 21% died.
Jin, J.-M. et al. (2020)	Wuhan Union Hospital, China	43 patients	While men and women have the same prevalence, men with COVID-19 are more at risk for worse outcomes and death, independent of age.

Table 1: Literature Review

Chapter 3

METHODS:

Research Question:

- What is the Effect of Sex differences in the Susceptibility, Severity, and Outcomes of Coronavirus disease positive patients admitted in to the hospital?

Study Location:

- This Prospective observational study is conducted at The Mission Hospital, a 350-bed super-specialty hospital located in Durgapur, West Bengal, India.

Inclusion Criteria:

- COVID 19 positive cases who were admitted in to MICU, CCU, ICU wards.
- COVID 19 positive cases with other existing co-morbid conditions such as HTN, DM etc., who were admitted into Medical Intensive Care Unit (MICU), Corona Care Unit (CCU), Intensive Care Unit (ICU) wards.

Exclusion Criteria:

- All other communicable diseases, non-communicable diseases, Acute conditions, other Emergency cases were excluded.

Study Duration:

- The present study was conducted for **3 months** between April 6th and June 10th, 2021.

Sample Size:

- **84** COVID positive patients were observed continuously for 3 months.

Research Design:

- Prospective Observational Study.

Data collection type:

- Patients' complete details were collected in the form of Electronic Medical Records (EMR) which were studied to evaluate the research question.

Data collection method:

- Specially designed data collection form was used to collect the patient's details from admission to the discharge point.
- Data is later/parallelly been entered into the Electronic Medical Records.

Analysis:

- The data was analysed with the Microsoft EXCEL.
- Tabular plots were drawn.
- Percentage calculations
- Comparative analysis

Ethical consideration:

- The data collected was handled with confidentiality; permission to carry out the project was obtained from the head of The Mission Hospital.

Chapter 4

Methodology:

This Prospective observational study was conducted at The Mission Hospital, a 350-bed super-specialty hospital located in Durgapur, West Bengal, India, to study the Effect of Sex differences in the Susceptibility, Severity, and Outcomes of Coronavirus disease positive patients admitted into the hospital.

The study was included COVID 19 positive cases and with other existing co-morbid conditions such as HTN, DM etc., who were admitted in to Medical Intensive Care Unit, Corona Care Unit, Intensive Care Unit wards. The study excluded all other communicable diseases, non-communicable diseases, Acute conditions, other Emergency cases. The study was carried out for 3 months between April 6th and June 10th, 2021, analysing 84 COVID positive patients closely under medical supervision.

To carry out the study permission was obtained from the head of The Mission Hospital. The data collected was handled with confidentiality; for analysis a specially designed data collection form were used to collect the patient's details from admission to the discharge point, which is later/parallelly been entered in to the Electronic Medical Records, these records were evaluated to compare the covid differences in the men and women. The data was analysed with the Microsoft EXCEL making Tabular plots and calculated percentage variations for specific data and comparative analysis was done.

Chapter 5

Results:

Patient's Distribution:

A total of 84 covid patients were monitored for 3 months between April 6th and June 10th, 2021. All the information about these patients were recorded in to the EMRs, each record was specific to each patient. Out of 84 patients there were 49 male patients and 35 female patients. The following graph gives the information about the patients' distribution based on gender.

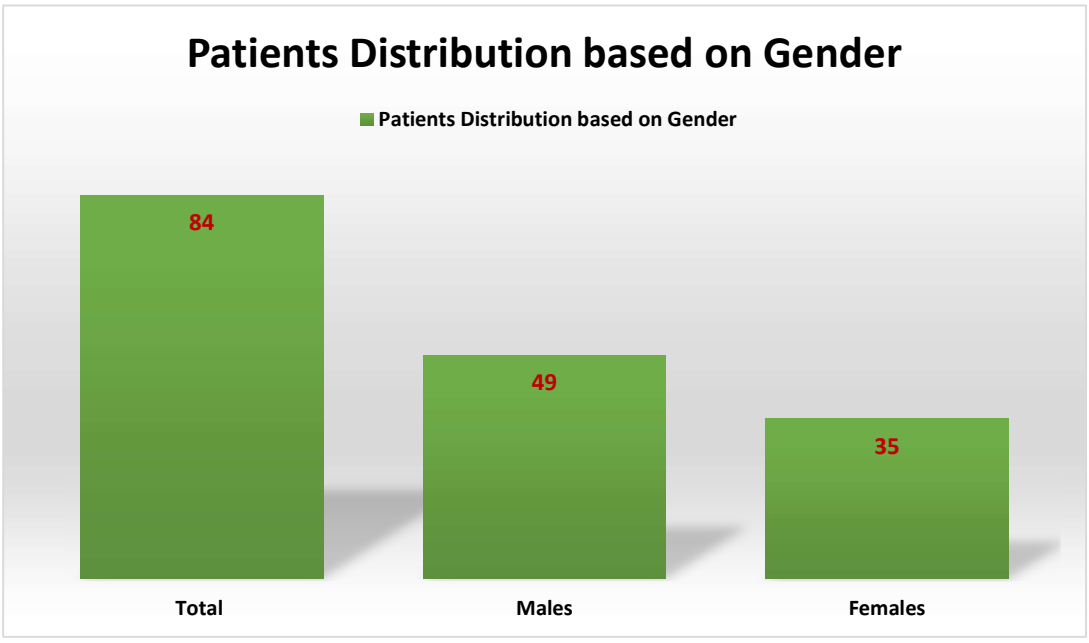

Fig. No. 1: Patients distribution based on gender.

Patients Distribution based on Age:

Out of 84 patients, most patients were identified between the ages of 43 and 64, and the other were starting from 30 years to 82 years. However, the age distribution is not clearly noticed as most of the patients ages were just a guess by their attendees and not exact as they were not recorded their dates of birth precisely at their point of birth, which was mentioned by the attendees themselves. 23 patients fell under 50 – 60 years of age, making its highest percentage share in the population under study, followed by 20 patients from the age group 60 -70 years makes the second highest share. Third share of the age group was 40 – 50 years with 18 patients. This chart includes both the genders no differentiation was made with gender differences.

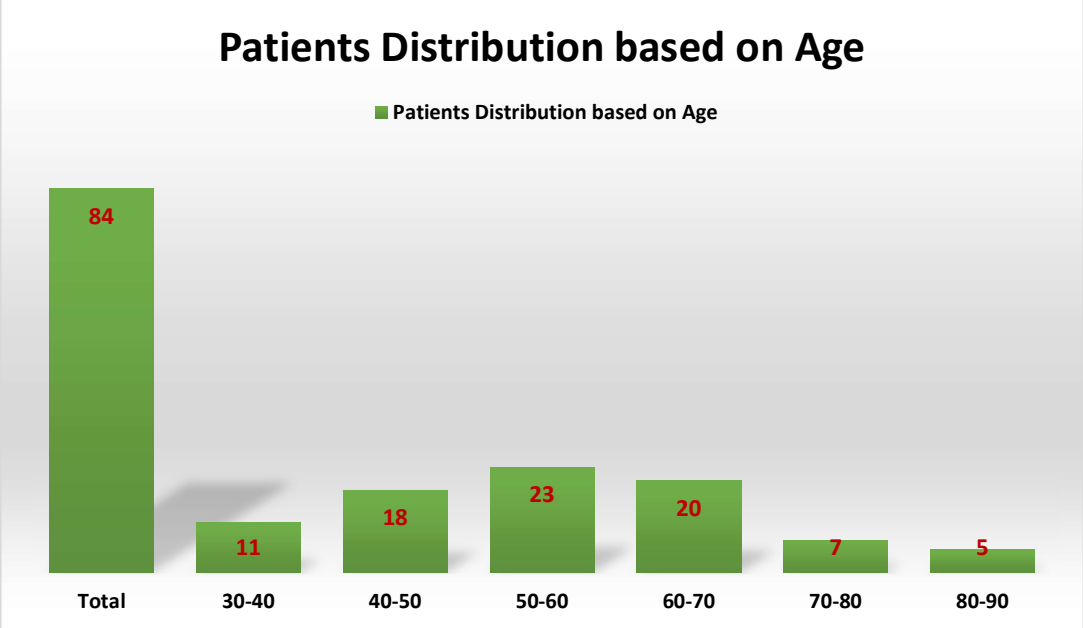

Fig. No. 2: Patients Distribution based on Age.

Patients Distribution based on Covid severity:

Out of 84 patients, most male patients were into serious medical interventions, and this continued even in the mortality rate which was happened more in the males. Covid severity levels were distributed into the following categories such as mild, moderate, severe and critical. Severe and critical cases were needed the oxygen supply either by oxygen masks or by ventilators. Most severe and critical cases were noted in the male population.

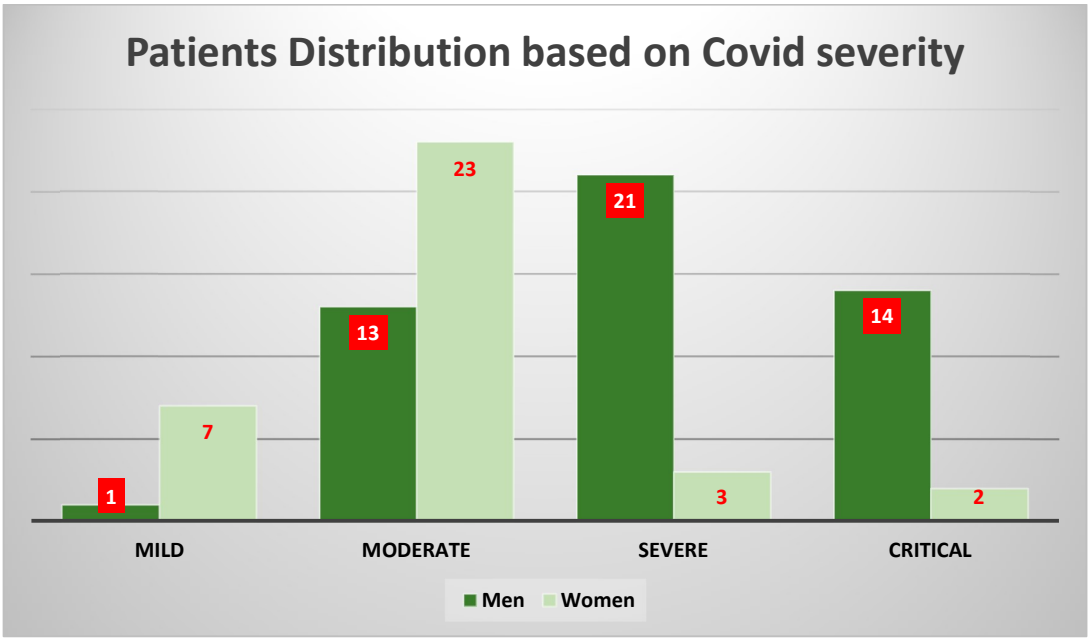

Fig. No. 3: Patients Distribution based on Covid Severity.

Patients Distribution based on Co-Morbidities:

The impact of co-morbidities was also well established in the male population, the severity of the covid is directly proportional to the existing diseases in the men's population. The other diagnoses apart from the covid noted were Hypertension, Diabetes Mellitus, Renal Failure, Existing Lung damage, Heart stroke and Brain stroke.

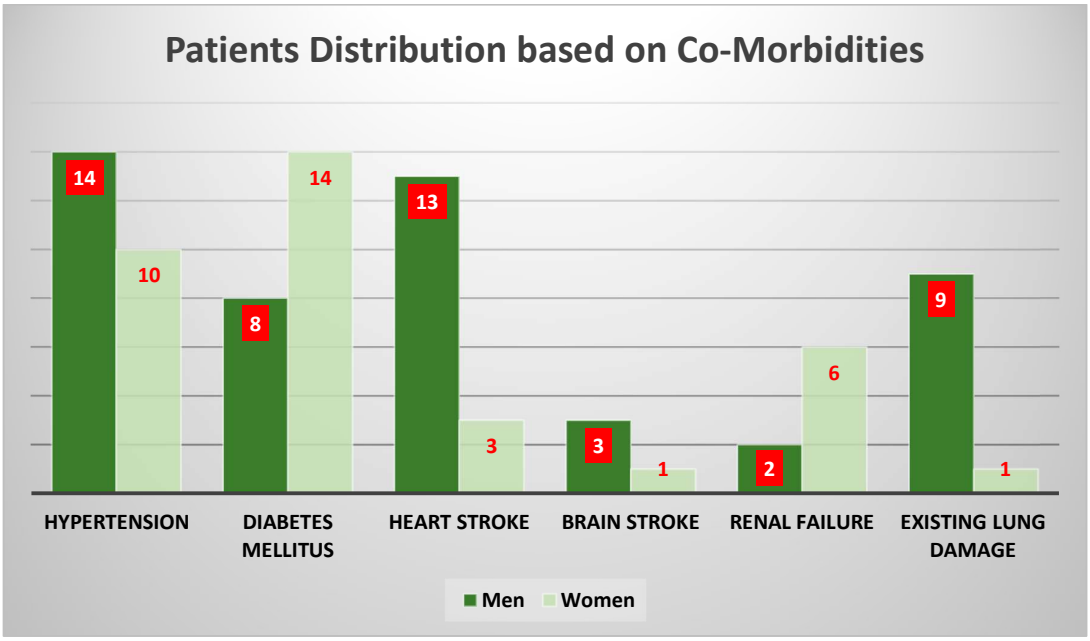

Fig. No. 4: Patients Distribution based on Co-Morbidities.

Treatment received:

The following medicines list were generally prescribed in the treatment of the patients who were admitted in to the MICU, CCU and ICU wards, however each patient's medicines list was individualised based on their health status and existing co-morbidities. Most of the medicines were in the injection formulations and were monitored for outcomes and adverse reactions carefully throughout the patient's admission period. All the medicines were prescribed following the covid treatment protocol guidelines proposed by the ICMR and WHO. Other medicines which were already being used by the patients for their co-morbidities were continued as such and were stopped whenever needed to sustain the life of the patients.

Sl.No	DRUGS	DOSE	ROUTE	FREQ
1.	INJ TARGOCID	400	IV	TDS
2.	INJ ENOXAPARIN	40MG	S/C	OD
3.	TAB PULMOCLEAR	100/600	ORAL	BD
4.	TAB ZINCONIA	50	ORAL	OD
5.	TAB LIMCEE	500	ORAL	BD
6.	INJ SOLUMEDROL	125	IV	TDS
7.	INJ PAN	40	IV	OD
8.	INJ TOCLIZUMAB	400	IV	STAT
9.	INJ MEROPENAM	1GM	IV	TDS
10.	INJ FORCAN	200MG	IV	OD
11.	MDI DUOLIN	2 PUFFS	NASAL	TDS
12.	MDI FORACORT	2 PUFFS	NASAL	BD
13.	INJ H.ALBUMIN	20%	IV	OD
14.	INJ REMDISIVIR	200 STAT	IV	OD
16.	TAB ZAPIZ	0.25MG	P/O	ODHS
17.	TAB SHELCAL-XT	1TAB	P/O	OD
18.	MDI DUVA	2PUFFS	NASAL	OD
19.	INJ LANCTUS	12 UNITS	S/C	OD@8AM
20.	INJ FIAS-P	8-6-6	S/C	TDS
22.	T.DEXONA	8MG	P/O	OD

Table 2: Treatment Chart in MICU, ICU, CCU

Discharge Medications:

After being relived from the covid severity, patients were shifted to general wards to monitor the health for 48 hours and later were discharged if all the parameters were normal. Before discharging the patients were properly counselled along with their attendees on how to use the medicines, lifestyle modifications and diets to be followed. The following medicines list were usually used as the discharge medication; however all the prescriptions were customised based on the patient health status.

Sl.No	DRUGS	DOSE	ROUTE	FREQ
1.	TAB. IVERMECTIN	12 mg	ORAL	OD-5Days
3.	TAB DOXYCYCLINE	100 mg	ORAL	BD-5Days
4.	TAB PANTOPRAZOLE	40 mg	ORAL	OD-5Days
5.	TAB PARACETAMOL	500 mg	ORAL	TDPC-3Days/SOS
6.	TAB VITAMIN C	500 mg	ORAL	BD
7.	TAB VIT. D3	60,000 units	ORAL	Weekly once * 2
8.	TAB ZINC	50 mg	ORAL	BD 2 weeks
9.	POVIDINE IODINE	1%	GARGLE	BD 2 weeks
10.	TAB LEVOCETRIZINE	5 mg	ORAL	1 Tab SOS

Table 3: Discharge Medications List

COVID Mortality:

In the span of 90 days a total of 58 deaths were recorded in the hospital, out of 58 deaths male deaths surpassed the females by 24. Total of 41 deaths were seen in the male population and 17 deaths were noticed in the case of females. The following graph illustrates the mortality of the patients.

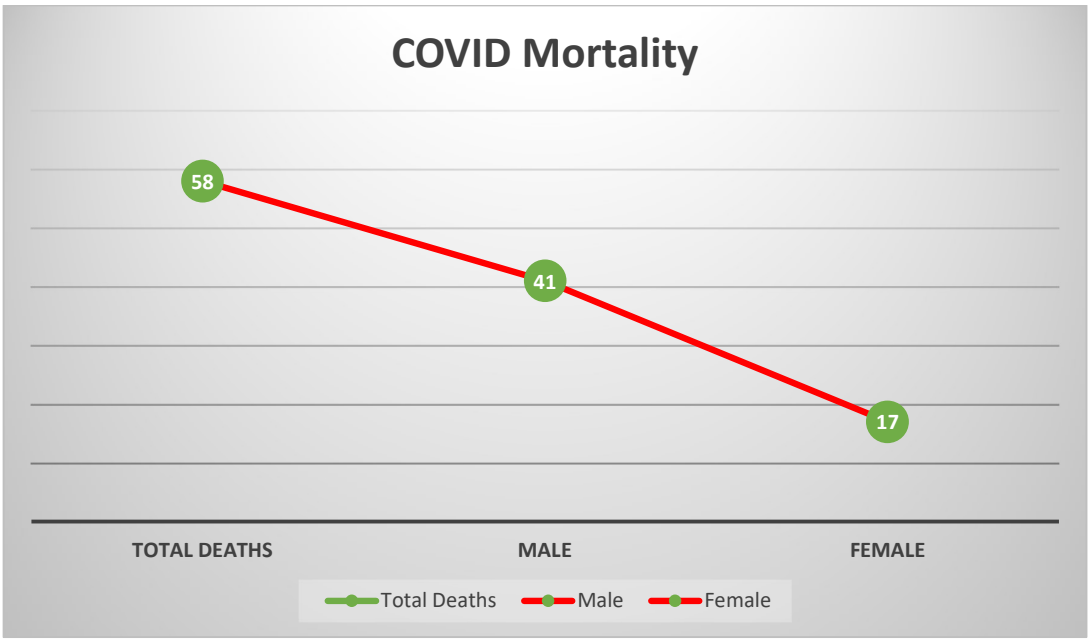

Fig. No. 5: COVID Mortality

Mortality Cause:

The mortality is found to be more from the consequences but not directly from the COVID itself. The following illustration provides the details of the various common causes for the death of the patients. The major cause identified was COVID Pneumonia with Acute Respiratory Shock and Multiorgan dysfunction syndrome.

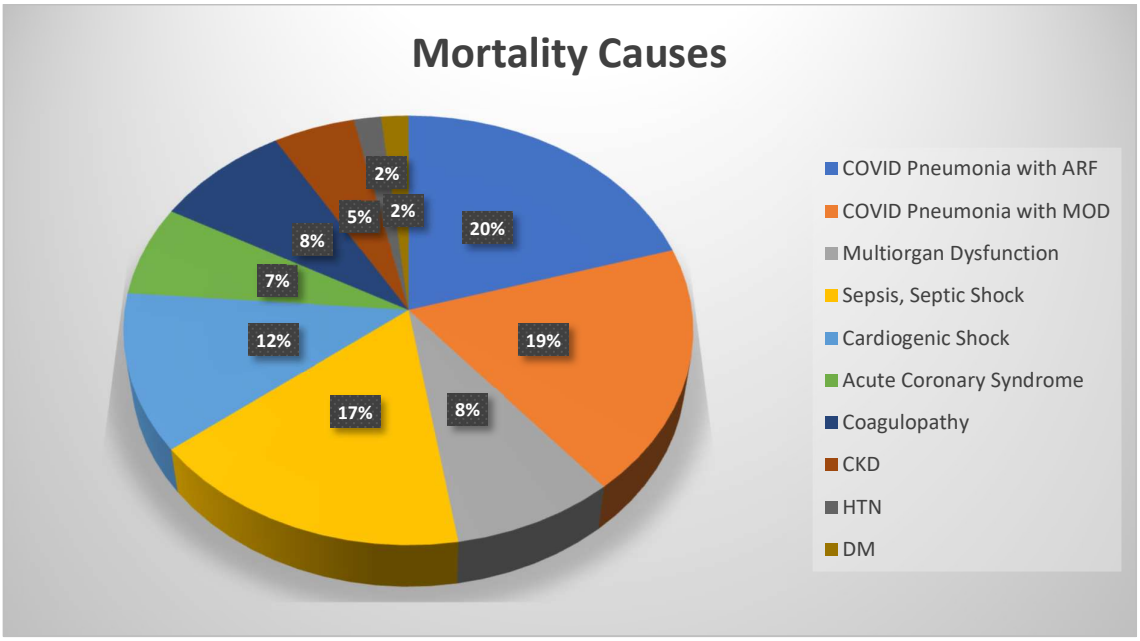

Fig. No. 6: Causes of Mortality

Mortality Rate:

The total Mortality Rate / Death Rate identified for the population admitted into the hospital during 3 months was **69.04%**, of which male death rate was **48.8% and** female death rate was **20.23%.**

Chapter 6

Discussion:

As the COVID-19 pandemic threatens the global health care system. Research has shown that there are a lot of differences between a male and a female-COVID-19 patients, the incidence, the severity of the disease and the mortality rate; a high incidence, sensitivity, and the mortality rate was observed among men in many countries have, therefore, to the male sex, is a poor prognostic factor, as the men's are more prone to viral infections, in particular, of the SARS-CoV-2, as a result of the differences in the innate immune system, steroid hormones, and factors related to the sex chromosomes.

The present study clearly demarcates the evidence suggested by the global research that men are more susceptible to the COVID. Out of 84 patients, 49 males and 35 females were observed. Most of the patients were identified from the age groups between 40 and 70 years of which peak was identified in the ages between 50 and 60. Most critical and severe cases were identified in the male population and females were highly noted in the mild and moderate cases. The existing co-morbidities were HTN, DM, Heart Stroke, Brain Stroke, Renal Failure, and existing Lung damages. Males outstand with all conditions except for DM, which was ranked by the females. The admitted patients were treated with the medicines which were approved by the ICMR and WHO. Medicines were prescribed based on the patients' individual necessaries and were closely monitored for the serious outcomes. A total of 58 deaths were recorded, of which of 41 deaths were seen in the males and 17 deaths in the females. The total Mortality Rate / Death Rate identified in 3 months was **69.04%**, of which male death rate was **48.8% and** female death rate was **20.23%.** The death rate clearly provides the information about how the male population is susceptible to the COVID and its consequences**.** The major

cause of the deaths were precisely identified were COVID Pneumonia with Acute Respiratory Failure, COVID Pneumonia with Multiorgan Dysfunction, Sepsis, Septic shock and cardiogenic shock.

The global studies also suggests that the influence of gender on the SARS-CoV-2 infection, as well as the severity and outcome of COVID-19, it is now generally accepted proof for this. Men and women differ in terms of clinical severity and the mortality rate of COVID-19, several pieces of evidence to suggest that it did. The social habits, customs, and related diseases are the differences between the two sexes, and hygiene practices and are more likely to affect women than men, while in the smoker, and the related diseases are more common in men than in women. Viral penetration is facilitated by the men who are in possession of a genetically higher ACE2 expression in the lung and increased testosterone levels of expression of the TMPRSS2 than in women, whereas the oestradiol increases ACE2 activity in females, which can help to protect women against heart disease. Men, too, showed a genetically related to increased susceptibility to infection than the females, which, in turn, make use of a more efficient and effective regulation of the immune system in comparison to men. In addition, the direct pro-inflammatory effects of testosterone, and the anti-inflammatory effects of oestradiol and lead to an increased inflammatory response in men compared to women. Finally, though men and women do not show any difference in genetic predisposition to thromboembolism, men at any kind of age have a greater thrombotic risk than women, in women the thrombotic risk is lower at fertile age and increases at menopause and/ or under oestrogen therapy. In elderly patients inflammation leads to an immune defective, proinflammatory, and prothrombotic state, which even worsens, in men more than in women, the course of COVID-19.

Chapter 7

Limitations:

The present study is conducted in a very short period and few samples were analysed which is however evident in identifying the predisposing differences in male and female populations, vast sample size and longer periods would provide the better evaluations, and the hormonal effects were not monitored clearly but only taken into considerations while writing the discussion points.

Chapter 8

Conclusion:

The present observational study concludes that immune dysregulation is more severe in male than in female COVID-19 patients, which in turn due to the sex-related differences in the immune activation 'set point,' happening to exert different disease severities and mortalities in men and women. This is an evidence suggests to the local and global research that men are more prone to the COVID and are more vulnerable to the Susceptibility, Severity, and Outcomes of the Corona Virus Disease.

Chapter 9

Suggestions:

- Emphasizing sex-dependent diagnostic and treatment methods are needed to provide effective therapy considering sex as a biological variable in COVID-19.
- Conducting national level pilot studies or survey studies to precise the same results.
- Researchers and policy experts agree that sex- disaggregated data on COVID-19 infection and case fatality rate are needed to develop gender-equitable solutions to this pandemic.
- social factors linked to COVID-19 exposure and mortality need to be identified, to enable exploration of intersectional differences.

Chapter 10

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