Summer Training

at

Rukmani Birla Hospital (CK Birla), Jaipur

10 May – 2, July 2021

A Report on

Effects of Remdesivir, Dexamethasone and Itolizumab on covid treatment in terms of clinical outcomes in patients

by

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MBA Hospital and Health Management

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IIHMR UNIVERSITY

CK BIRLA HOSPITALS | RBH

RBH/2021/July/HRD/2611

Date – 24th July, 2021

To whom so ever it may concern

This is to certify that Dr. Himani Bhati has successfully completed her internship training in Medical Admin Department from 10th May 2021 to 2nd July, 2021.

We found her sincere, punctual & hardworking. We wish her every success in her future and career.

Anupama Sharma
Unit HR Head
Human Resources

ACKNOWLEDGEMENT

First of all, thanks and praise to almighty for showering his blessings throughout my journey to complete the project.

I would like to express my sincere gratitude and thanks to the summer training opportunity I had with CK Birla hospital, RBH, Jaipur, Rajasthan. It was a great honor and experience to work with such splendid personalities.

I am indebted to Dr. Suhasini Jain (Medical superintendent) and Dr. Aleena Jana (Medical administration) for providing me the opportunity to perform the research and for guiding me throughout the training. I would also like to thank Dr. Abhimanyu Sethi for his guidance. It was a great privilege to work and learn under their leadership.

Besides this a very big thanks to IT department and medical record department for cooperating with me.

Most importantly I would like to express my gratitude and thanks to my mentor Dr. P.R. Sodani (President, IIHMR University, Jaipur) for his constant guidance and support throughout the study.

Sincerely,
Dr. Himani Bhati
Place: CK Birla Hospital, Jaipur
Date:

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ABBREVIATION

ACLS	Advanced Cardiovascular Life Support
CSSD	Central Sterile Supply Department
CTVS	Cardiothoracic and Vascular Surgery
DMLT	Diploma in Medical Laboratory Technology
DOR	Discharge on Request
ECG	Electro Cardiography
EEG	Electro Encephalogram
ER	Emergency
HDU	High Dependency Unit
IVF	Invitro Fertilization
IPD	In Patient Department
LAMA	Leave Against Medical Advice
MRI	Magnetic Resonance Imaging
MICU	Medical Intensive Care Unit
MRD	Medical Record Department
NICU	Neonatal Intensive Care Unit
NABH	National Accreditation Board of Hospitals and Healthcare providers
OPD	Outpatient Department
PFT	Pulmonary Function Test
RBC	Red Blood Cells

RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
SICU	Surgical Intensive Care Unit
SCBU	Special Care Baby Unit
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus - 2

Introduction

The Calcutta Medical Research Institute (CMRI), the BM Birla Heart Research Centre (BMB), and its most recent initiative, Rukmani Birla Hospital (RBH), all belong to CK Birla Hospitals, which have set milestones in the healthcare industry. Three interconnected concepts bind the hospitals together: Clinical Excellence, Ethics, and Patient Centricity. These operating approaches have proved critical in allowing hospitals to expand and provide treatment to those in need. CK Birla Hospitals has three locations in Kolkata and Jaipur, with a total of 800 beds and comprehensive outpatient and inpatient treatments. The hospitals continue to set new benchmarks in Cure and Care, with a purpose to provide high-quality healthcare to all people, backed by cutting-edge technology and modern infrastructure.

Rukmani Birla Hospital is a multispecialty hospital with 230 beds that provides comprehensive in-patient, out-patient, and emergency care. Clinical excellence, ethical conduct, and a patient-centered approach are the three guiding principles. RBH includes a total of 24 specialised healthcare departments, each equipped with cutting-edge medical technology and staffed by a team of highly qualified doctors and nurses. It was founded in Jaipur in the year 2014. It is a NABH-accredited Indian quality council. It can be found at Gopalpura Bypass Road, near the Triveni Bridge, in Jaipur, Rajasthan, 302019. Rukmani Birla Hospital in Jaipur is equipped with cutting-edge technology and ergonomically built interiors. There are six modular OTs, an advanced cath lab, a modular IVF and diagnostic lab, a big 12-bed emergency ward, a 15-bed dialysis unit, and 64 critical care beds. Patients have access to fully prepared life-saving ambulances 24 hours a day, seven days a week.

Vision: To provide the highest level of patient care and clinical excellence.

Mission: To set the bar for providing an incomparable patient experience through clinical and service excellence in an exclusive environment that embraces innovation and quality, as well as compassion, accountability, and transparency.

Quality Policy Statement: To maintain the highest standard of quality in the services provided at the hospital.

Commitment to quality: To continually improve our human and technology resources in accordance with the finest global trends in medical science.

Hospital has the following departments:

✓ Anesthesiology	✓ CTVS	✓ Dental Services	✓ Endoscopy
✓ Cardiology	✓ Critical Care Services	✓ Dialysis	✓ Emergency
✓ Endocrinology	✓ General Medicine	✓ General surgery	✓ Gastroenterology
✓ GI Surgery	✓ Psychiatry	✓ Neonatology	✓ Nephrology
✓ Neurology	✓ Neurosurgery	✓ Obstetrics & gynecology	✓ Otolaryngology (ENT)
✓ Pediatrics	✓ Plastic and Reconstructive surgery	✓ Respiratory medicine (Pulmonology)	✓ Urology

Rehabilitative Services:

- Osteopathy
- Speech and Language
- Physiotherapy

Support Services:

- Ambulance
- Blood Storage Centre
- Health Checkup
- Pharmacy
- Nutrition
- Food and Beverages

- Mortuary
- ATM

Diagnostic Services:

Services for diagnostic imaging

• Bone density measurement

• CT scan

• Mammography

• MRI • Ultrasound

• X-ray

Laboratory Services

- Biochemistry
- Clinical Pathology
- Cytopathology
- Hematology
- Histopathology
- Immuno Assay
- Microbiology and Serology

Other Diagnostic Services

- Audiometry
- ECG
- Echocardiography
- EEG
- EMP/EP
- Holter Monitoring
- PFT
- Spiro logy

- Tread Mill Testing
- Urodynamic Studies

OBSERVATIONAL LEARNINGS

Outpatient Department (OPD)

Basically, OPD of this hospital is divided into two parts. Half of the OPD is in ground floor and half is in the basement. There are 14 consultation chambers in OPD. OPD timings are 10 AM to 4 PM. The sitting capacity is approximately 150. Total number of front desks are 5. The system they follow for appointment is first come first serve. Per day OPD is about 250.

Inpatient Department (IPD)

There is total 230 beds in the hospital. These beds are segregated from 1st to 5th floor.

- Medical ICU (MICU)- 9 beds
- Neonatal ICU (NICU)-6 beds
- Surgical ICU (SICU)-9 beds
- Surgical Care Baby Unit (SCBU)-5 beds
- High Dependency Unit (HDU)-5 Beds
- Major Operating Room- 6 OT's
- Labor Room- 2 beds
- Intensive Cardiac Care Unit- 15 beds
- General Ward- 22 beds
- Single Bedded rooms- 21
- Double Bedded Room- 24

Radiology and Imaging Services

The Radiology Department of Rukmani Birla Hospital is in the basement.

It consists of:

- CT Scan – 1 Machine
- MRI – 1 Machine
- X-ray – 2 (1 portable and 1 fixed)
- Mammography – 1 Machine
- Cath Lab – 1 Machine
- Bone Densitometry – 1 Machine
- Ultrasonography – 2 Machines (1 portable and 1 Fixed)

Dialysis Unit

Dialysis unit is on ground floor. There is total 15 beds and 15 Dialysis machines attached with them 3 more portable dialysis machines are available for ICU. Basically, dialysis is a process in which excess water and waste from blood is removed due to improper functioning of kidney. A patient comes and consult the nephrologist and their treatment is planned. The schedule is made, and vitals are checked including weight. Patient with communicable diseases is kept in isolation rooms.

Blood Bank

Blood bank is on 1st floor. It is licensed and approved by Drug Control Organization, Rajasthan.

Blood bank consists of-

- Whole human blood IP
- Packed RBCs IP
- Platelet concentrate IP.
- Fresh Frozen Plasma IP
- Cryoprecipitate USP
- Plateletpheresis SDP

Laboratory Department

Laboratory is located on first floor. The number of staff in this department is 18. Minimum required qualification is DMLT.

- Clinical Staffs- 8
- Microbiology staffs- 4
- Sample collection staffs- 4
- Histopathology staffs- 2

Emergency Department

In this department there are 2 ambulances with ACLS. There is total 6 beds in ER. There are in total 4 staffs in ER. equired qualification is graduation. Continuous training and education are given to the staff regarding all the procedures. In case of medico-legal cases they follow the procedure in accordance with the law.

Medical Intensive Care Unit (MICU)

- Location- First Floor
- Type- Cubical
- Manpower- 35
- Number of beds- 14
- Isolation bed- 1
- Indicators:
- Medication error
- Identity error
- Patient safety
- Infection control

Operation Theatre (OT)

OT is located on 1st floor. There are in total 6 modular OTs.

Pharmacy

For IP Pharmacy- Each and every requirement comes in form of E-Prescription generated by concern doctor and nursing staff as per patient's need.

Medical Record Department (MRD)

Medical record department or Health information management is the department which manages health information data and make certain of its quality, security, accuracy, and accessibility both in electronic system and paper. There is numerous allocating system to code and categorize patient's details for remittance purpose. File records and databases are also used to maintain patients medical as well as treatment histories.

Dietary (F&B Department)

It is on the ground floor, and it is an outsourced company named Life pillars.

CSSD

CSSD (Central Sterile Supply Department) is the most important department of the hospital. It performs various functions and is located on the ground floor of Rukmani Birla Hospital, Jaipur.

Zones in CSSD-

- Decontamination
- Clean
- Sterile

Color coding for the zones-

- Decontamination – Red
- Clean – Blue
- Sterile – Green

Colors help to eliminate confusion, simplify training, give monitoring, and reduce cross contamination. This is how a well-executed system works.

1) Reusable tools are available in a variety of colors, with each color denoting a distinct usage for a specific section of the hospital, such as the patient's washroom, patient room, ICU, and operating rooms.

2) These tools are only utilized in the designated area of a second room.

3) Before being re-used, used tools are cleaned according to CDC recommendations for Blood Born Pathogens.

Medical Gases

Medical gas supply systems are used to deliver specialized gases and their combinations to various regions of hospitals and other healthcare institutions. Product handle by such system typically include.

Oxygen

Air for medical purposes

Nitrous oxide

Nitrogen

Carbon dioxide

Vacuum for medical purposes

Waste anesthetic gas disposal (US) or Anesthetic gas scavenging system (ISO)

Floor wise facilities available

Basement- Outpatient Department, Radiology, A/c control plant, Teaching room, Mortuary

Ground Floor- Emergency, Outpatient Department, IP Billing, Dialysis, Pediatric care, Staff cafeteria, F&B Department, Linen, Preventive Health Checkups, Report’s delivery, TPA.

First Floor- Operation Theatre, Intensive care unit, CSSD, Human Resource, Marketing Finance.

Second Floor- General ward, Blood Bank, Laboratory, nursing admin, waiting Lounge.

Third Floor- Labor room, Maternity triage, IPD rooms.

Fourth Floor- IPD rooms.

Fifth Floor- IPD rooms.

PROJECT

Effects of Remdesivir, Dexamethasone and Itolizumab on covid treatment in terms of clinical outcomes in patients.

Introduction: Corona virus Disease is a communicable disease caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The symptoms of covid-19 may vary from mild, moderate to severe illness. It may appear in the time duration of 2-14 days after infection. Possible symptoms are symptoms of upper respiratory tract infection like fever, cough, SOB, breathing difficulty, sore throat, congestion, or runny nose etc., and others are nausea, vomiting, body ache, headache, and diarrhea etc.

First known case was found in Wuhan, China in December 2019 and in India first case was identified in January 2020 in Kerala. Since then, the disease had spread all over the world leading to an ongoing pandemic. Till date in India around 3,03,62,162 people are infected and around 3,98,487 people died due to this covid-19 disease.

Many experimental medications are being actively under trial. Drugs like Hydroxychloroquine & lopinavir/ ritonavir were thought to be effective in initial period of the pandemic but later they found to be ineffective. Then an antiviral drug called Remdesivir is used but it also seems to be ineffective. Although, it failed in many trials initially and did not show any decrease in mortality. But after reanalyzing Remdesivir, studies came up with that it can lead to reduction in mortality. In severe cases or in patients who are on mechanical ventilator support, Dexamethasone is highly recommended as it can lower the risk of death. As compared to other drugs dexamethasone is cheaper and is more effective in reduction of mortality.

Objective: To find out the probabilities of Remdesivir, Dexamethasone and Itolizumab in reducing the mortality and duration of stay in hospital of confirmed covid positive patients.

Literature Review: In an International Journal of Infectious Diseases a study on "Remdesivir and Systemic Corticosteroids for the treatment of Covid-19: A Bayesian re-analysis". They collected data from four trials of remdesivir consisting of 7322 patients and eight trials of corticosteroids consisting of 7557 patients. The results suggest that remdesivir and corticosteroids had a 4 percent and a 93 percent chance of lowering death in individuals who needed mechanical breathing, respectively. For patients who needed supplementary oxygen but didn't need mechanical ventilation, remdesivir and

dexamethasone reduced mortality by 81 percent and 93 percent, respectively. Finally, remdesivir and dexamethasone had a 29 percent and 4 percent chance of lowering death in patients who did not require oxygen assistance, respectively.

They concluded that, when employing a Bayesian analytic method, remdesivir had a poor likelihood of attaining a clinically relevant lowering in death rate, with the exception of patients who required supplementary oxygen but did not require mechanical ventilation. Corticosteroids were found to be more beneficial for individuals who needed oxygen support, particularly mechanical breathing. While more absolute studies are expected, this probabilistic assessment of the data will aid physicians, as well as guideline and policy makers, in making treatment decisions.

According to the New England Journal of Medicine, researchers organized a double-blind, randomized, placebo-controlled trial of intravenous remdesivir in people who were hospitalized as confirmed covid positive patients and had indications of lower respiratory tract infection. A total of 1062 patients were randomly assigned to Remdesivir or placebo, with 541 receiving Remdesivir and 521 receiving placebo. The trial found that remdesivir was more effective than placebo in reducing the betterment time for those who were hospitalized as corona positive and had indications of a lower respiratory tract sepsis or infection.

A study on Dexamethasone in individuals hospitalized with covid-19 was published in the same journal. In this trial, individuals who were hospitalized with Covid disease were randomly allocated to accept oral or dexamethasone intravenously (at a dose of 6 mg once daily) over a 10-day period, or to receive standard care alone. The key finding was a 28-day death rate. They gathered 2104 and 4321 patients, respectively, for Dexamethasone and patients who received standard care. The mortality rate among patients receiving invasive mechanical ventilation was lower in the dexamethasone group compared to those in the usual care group. Dexamethasone was found to decrease 28-day mortality in patients hospitalized with Covid-19 in contrast to those who received either invasive mechanical ventilator assistance or only oxygen at randomization, but no respiratory support.

Sample size: We took admission and discharge data of 321 patients from May 1st,2021 to June 8th, 2021, out of which 211 received Itolizumab or Remdesivir either with Dexamethasone or alone. And 101 patients did not receive any three of them. 9 patients are removed due to data error.

Criteria: The inclusion criteria for the study are hospitalized patients above 18 years of age who have confirmed RT-PCR for SARS-CoV-2 and chest image shows confirmed pneumonitis.

Exclusion criteria for study is the patient who did not admitted in the hospital with positive RT-PCR and who are not in the list of the patient who received remdesivir or dexona issued by the hospital or from outside.

Methods used to collect data: Secondary data is collected from the record of patients who were admitted and discharged in time duration of 1/05/2021 to 8/06/2021. First, we contacted to IT department to provide us the list of patients who received Remdesivir, Dexona and Itolizumab from the hospital. And we also went through the register for the number of patients who received the same from outside.

Study design: It is a retrospective cohort study in which we collected the existing data from the hospital of the patients who were admitted as SARS-CoV-2 positive patient in Hospital.

Results:

We took a sample size of 321 patients suffering from covid-19 admitted in the hospital in month of May. Out of which 211 patients received Remdesivir, Dexona and Itolizumab and who did not receive any three of them are 101. After comparing both the groups the mortality is 17.12% more in the group who did not received the mentioned drugs. And the group who received Remdesivir and Dexona had faster recovery and number of normal discharges is 19% more as compared to the other group.

From this data we can assume that these drugs are effective in reducing mortality by 17.12% and increasing recovery rate by 19%.

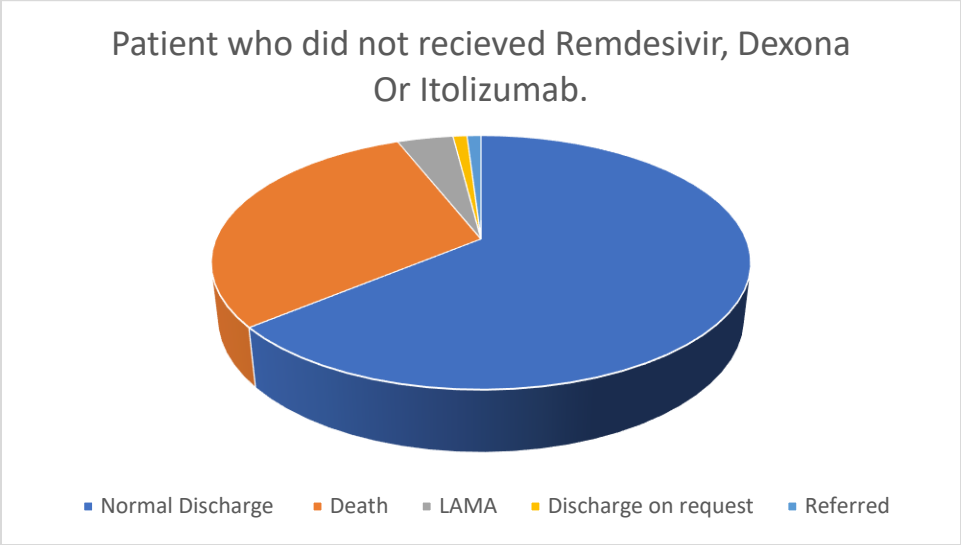
If we compare between Remdesivir, Dexona and Itolizumab that which one is more effective and better in reducing the mortality. According to the data observed 100% patients of Remdesivir group were normally discharged from the hospital. And patients who received only Dexona have 15.25% mortality and 76% patients were normally discharged.

Itolizumab show no such effect on patients as it has 60% mortality, and 40% patients were recovered which is less than the mortality rate.

These are probabilistic observations resulting due to sample size being too small to reach any final conclusion. For more definitive results we would have to do further study with larger sample size.

Patient who did not received Remdesivir, Dexona and Itolizumab

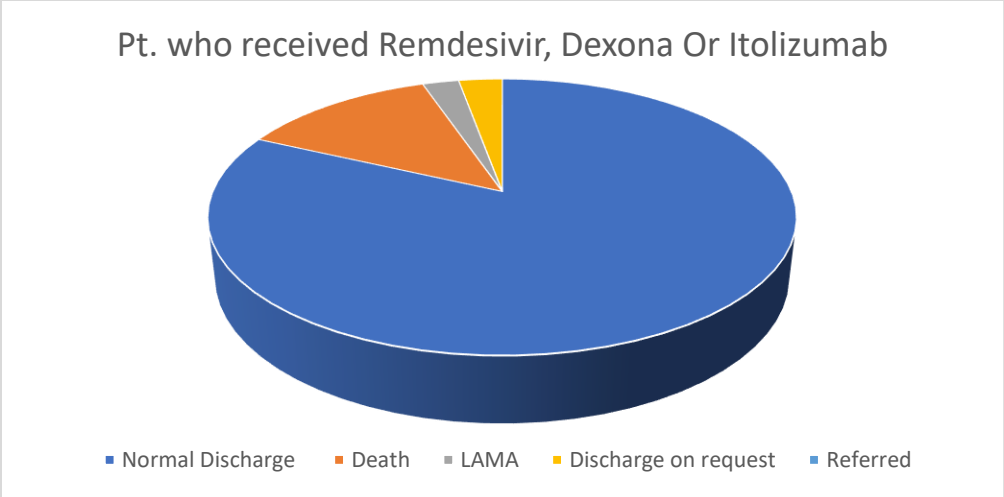
Total	**101**	**100%**
Normal Discharge	64	63%
Death	30	30%
LAMA	4	4%
Discharge on request	1	1%
Referred	1	1%



From the sample size of 321 patients, 101 are those who were not given Remdesivir, Dexona or Itolizumab out of which 63% were recovered and discharged from the hospital normally, and the mortality was 30%, 4% took leave against medical advice and rest 1-1% got discharged on request and referred to the other hospital respectively.

Pt. who received Remdesivir, Dexona or Itolizumab

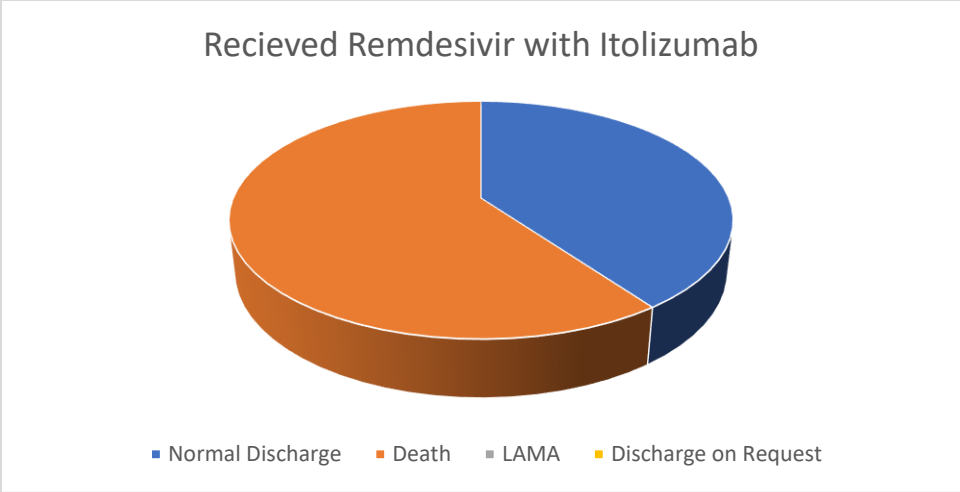
Total	**211**	**100%**
Normal Discharge	172	82%
Death	27	13%
LAMA	5	2%
Discharge on request	6	3%
Referred	0	0%



Out of 321 patients 211 were given Remdesivir, Dexona and Itolizumab from which 82% were recovered and discharged normally, mortality was 13%, 2% of them took leave against medical advice and 6% got discharge on request.

Received Remdesivir with Itolizumab

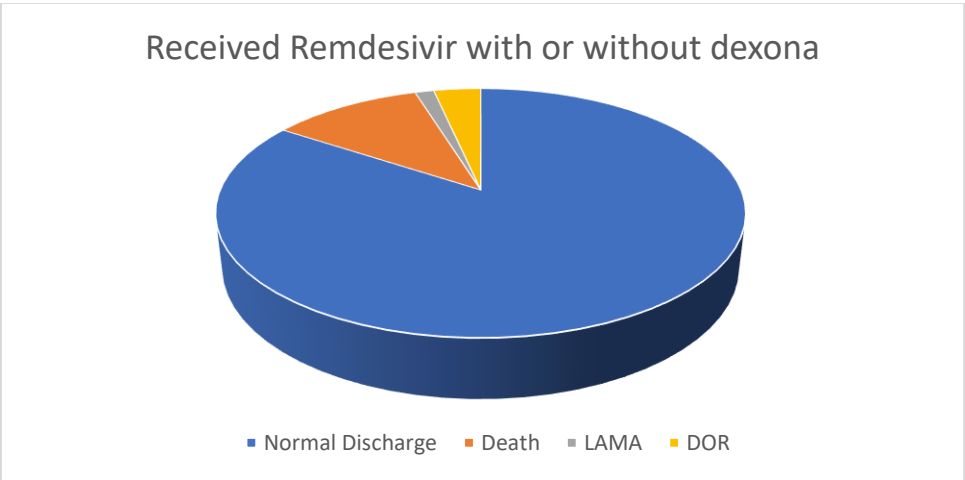
Total No. of Patients	**5**	**100%**
Normal Discharge	2	40%
Death	3	60%
LAMA	0	0%
Discharge on Request	0	0%



5 patients took Remdesivir with Itolizumab out of which 2 (40%) were normally discharged and 3 (60%) were dead, no one got LAMA or DOR.

Received Remdesivir with or without dexona

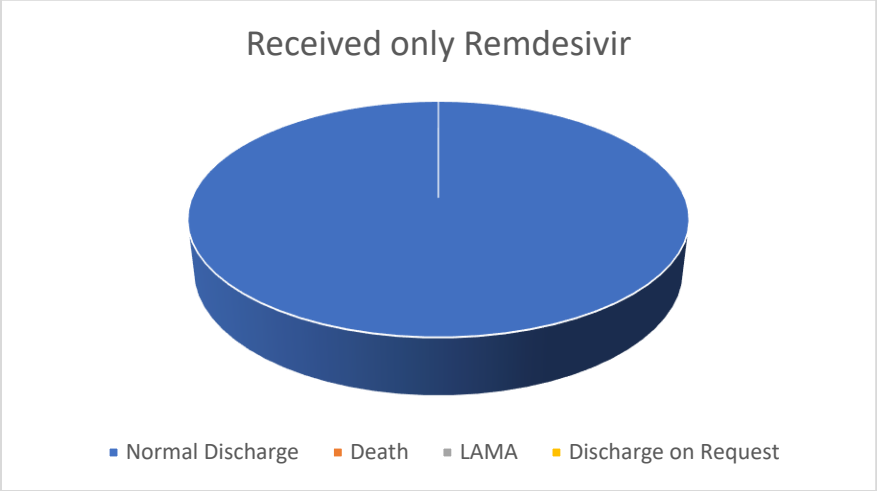
Total	**146**	**100%**
Normal Discharge	123	84%
Death	16	11%
LAMA	2	1%
DOR	5	3%



Total 146 patients were given Remdesivir with or without Dexamethasone out of which 84% were normally discharged and mortality was 11%, 1% took LAMA and 3% took DOR.

Received only Remdesivir

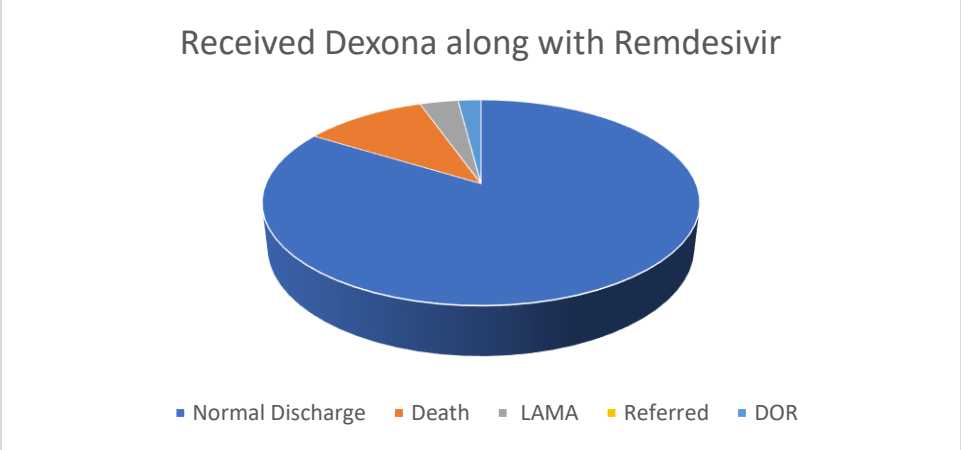
Total no. of patients	**45**	**100%**
Normal Discharge	45	100%
Death	0	0%
LAMA	0	0%
Discharge on Request	0	0%



The who received only remdesivir were 45, 100% of them was recovered and normally discharged from the hospital.

Received Dexona along with Remdesivir

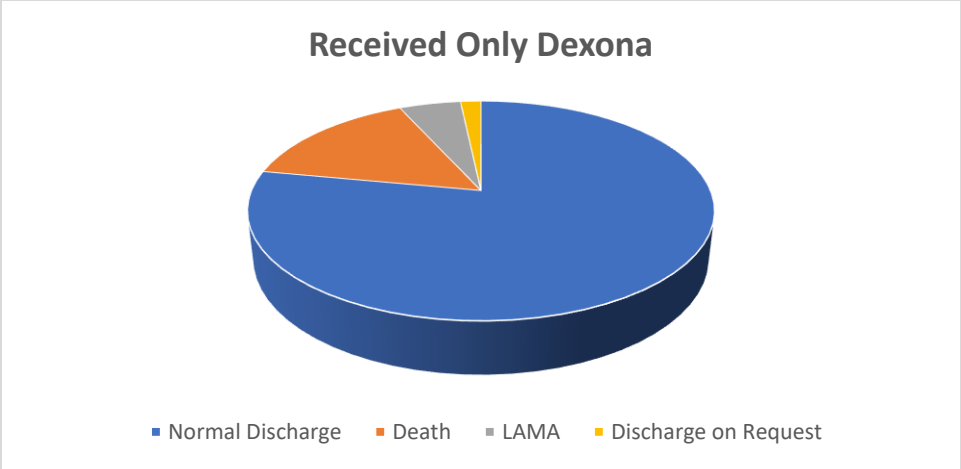
Total	**148**	**100%**
Normal Discharge	124	84%
Death	16	11%
LAMA	5	3%
Referred	0	0%
DOR	3	2%



148 patients received Dexona along with Remdesivir out of which 84% were recovered and normally discharged from the hospital and the mortality was 11%, 3% of them got LAMA and rest 2% are discharged on request.

Received Only Dexona

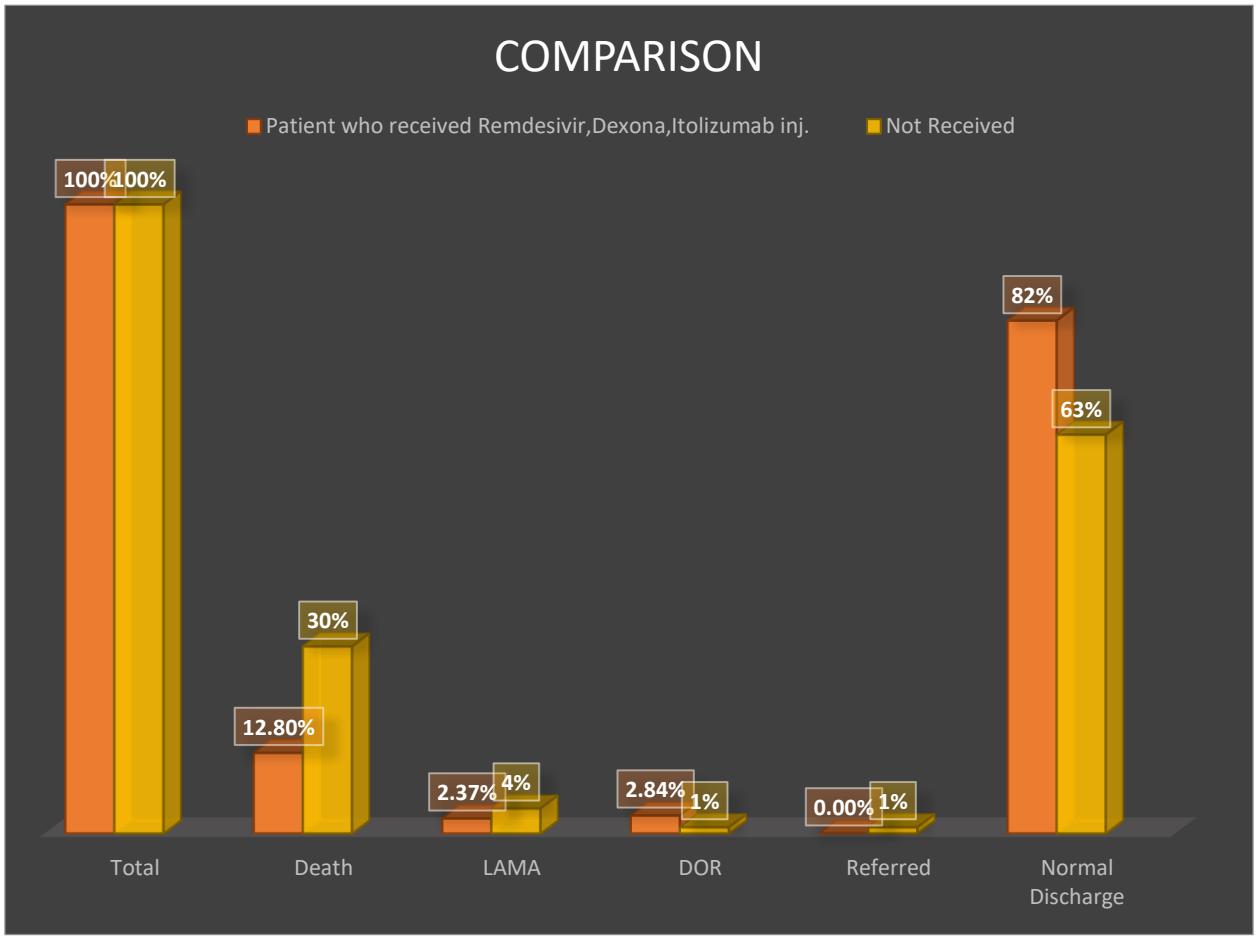
Total No. of Patients	**59**	**100%**
Normal Discharge	46	78%
Death	9	15.25%
LAMA	3	5%
Discharge on Request	1	2%



The patients who only received Dexamethasone were 59, 78% of them were normally discharged and mortality was 15.25%. 5% got LAMA and 2% are discharged on request.

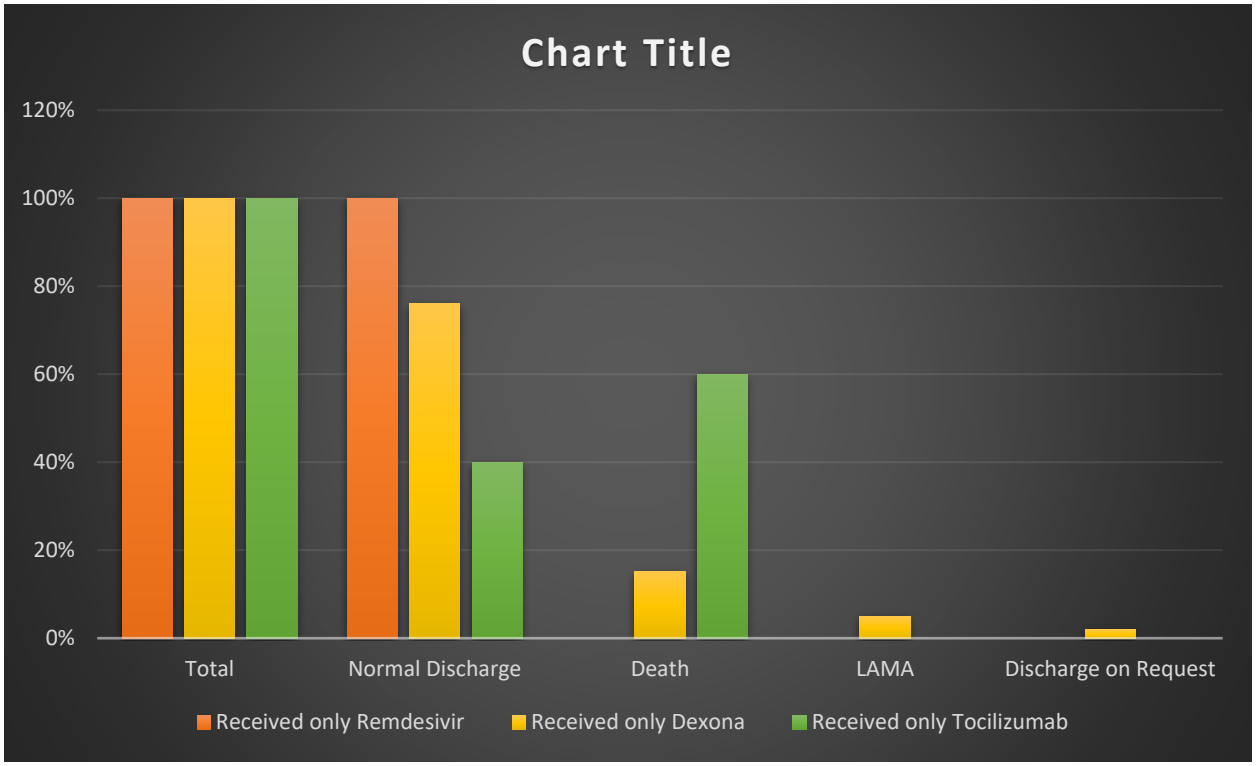
Overall comparison between the groups who received Remdesivir, Dexamethasone and Itolizumab Injections and who did not.

	Total	Death	LAMA	DOR	Referred	Normal Discharge
Patient who received Remdesivir, Dexona, Itolizumab inj.	100%	12.80%	2.37%	2.84%	0.00%	82%
Not Received	100%	30%	4%	1%	1%	63%



Trends observed in patients who received individual medication.

	Total	Normal Discharge	Death	LAMA	Discharge on Request
Received only Remdesivir	100%	100%	0%	0%	0%
Received only Dexona	100%	76%	15.25%	5%	2%
Received only Tocilizumab	100%	40%	60%	0%	0%



Conclusion: After completing this probabilistic study I concluded that the Itolizumab had very low probability of achieving meaningful results in the treatment of covid 19. Remdesivir and Dexamethasone seems more promising in reducing the mortality of the patients who needs supplemental oxygen with mechanical ventilation. When I analyzed alongside the data of Remdesivir and Dexamethasone the probability of significant effects of dexamethasone was lower. Comparatively remdesivir came up with more auspicious results in reducing the mortality of critically ill patients who were on mechanical ventilation. According to this data the length of stay of both the groups are almost same there is not much difference in length of stay of patients who received Remdesivir, Dexamethasone and Itolizumab & who did not receive. Although these are the probabilistic results because of the small sample size. It may vary if we take a larger sample size. For more definitive results we have to do further study with larger sample size.

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