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To Assess the Severity and Mortality among Covid-19 Patients after Having Vaccinated: A Retrospective Study

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ABSTRACT

The severity and mortality of COVID-19 cases has been associated with the Three category such as vaccination status, severity of disease and outcome. Objective:- presently study was aimed to assess the severity and mortality among covid -19 patients. Methods:- Using simple lottery random method 100 samples were selected. From these 100 patients, 50 patients were randomly assigned to case group and 50 patients in control group after informed consents of relative obtained. Patients in the case group who being died after got COVID-19+ whereas 50 patients in the control group participated who were survive after got infected from COVID-19+ patients. Result: -It has three categories such as a) Vaccination status:-For the vaccination status we have seen 59 patients were not vaccinated & 41 patients was vaccinated out of 100. (b)Incidence: - There were 41% patients were vaccinated whereas 59% patients were not vaccinated. (c)Severity: - In the case of mortality we selected 50 patients who were died from the Corona and I got to know that out of 50 patients there were 12 (24%) patients were vaccinated whereas 38 (76%) patients were non-vaccinated. Although for the 50 control survival group total 29(58%) patients were vaccinated and 21(42%) patients was not vaccinated all graph start. Conclusion:-we have find out that those people who got vaccinated were less infected and mortality rate very low.

KEYWORDS: *Covid -19, severity, mortality, vaccination, 2D and plasma therapy*

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INTRODUCTION

The name "coronavirus" is derived from Latin *corona*, meaning "crown" or "wreath", itself a borrowing from Greek *korṓnē*, "garland, and wreath". The name was coined by June Almeida and David Tyrrell who first observed and studied human corona viruses. The word was first used in 1968 by an informal group of virologists in the journal *Nature* to designate the new family of viruses. The name refers to the characteristic appearance of virions (the infective form of the virus) by electron microscopy, which have a fringe of large, bulbous surface projections creating an image reminiscent of the solar corona or halo.

This morphology is created by the viral spike peplomers, which are proteins on the surface of the virus. Coronaviruses are a group of related RNA viruses that cause diseases in mammals and birds. In humans and birds, they cause respiratory tract infections that can range from mild to lethal. Mild illnesses in humans include some cases of the common cold (which is also caused by other viruses, predominantly rhinoviruses), while more lethal varieties can cause SARS, and MERS. In cows and pigs they cause diarrhoea, while in mice they cause hepatitis and encephalomyelitis. Coronavirus disease 2019 (COVID-19), also known as the coronavirus, or COVID, is a contagious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The first known case was identified in Wuhan, China; in December 2019. The disease has since spread worldwide, leading to an ongoing pandemic.

Symptoms of COVID-19 are variable, but often include fever, cough, headache, fatigue, breathing difficulties, and loss of smell and taste. Symptoms may begin one to fourteen days after exposure to the virus. At least one third of people who are infected do not develop noticeable symptoms. Of those people who develop noticeable symptoms enough to be classed as patients, most (81%) develop mild to moderate symptoms (up to mild pneumonia), while 14% develop severe symptoms (dyspnea, hypoxia, or more than 50% lung involvement on imaging), and 5% suffer critical symptoms (respiratory failure, shock, or multi organ dysfunction). Older people are at a higher risk of developing severe symptoms. Transmission of COVID-19 occurs when people are exposed to virus-containing respiratory droplets and airborne particles exhaled by an infected person. Those particles may be inhaled or may reach the mouth, nose, or eyes of a person through touching or direct deposition (i.e. being coughed on).

Several testing methods have been developed to diagnose the disease. The standard diagnostic method is by detection of the virus' nucleic acid by real-time reverse transcription polymerase chain reaction (RT-PCR), transcription-mediated amplification (TMA), or by reverse transcription loop-mediated isothermal amplification (RT-LAMP) from a nasopharyngeal swab.

Preventive measures include social distancing, quarantine ventilation of indoor spaces, covering coughs and sneezes, hand washing, and keeping unwashed hands away from the face. The use of face masks or coverings has been recommended in public settings to minimize the risk of transmissions. Several vaccines have been developed and many countries have initiated mass vaccination campaigns. Management involves the treatment of symptoms, supportive care, isolation, and experimental measures. Retrospective Vaccine Effectiveness studies aim to emulate a randomized trial, in which vaccinated and unvaccinated individuals are comparable in their likelihood of being exposed to the virus and experiencing the outcome, apart from the key difference of whether they have received the vaccine.

A. ROLE OF PLASMA THERAPY FOR COVID -19 PATIENTS:-

Previously, medical professionals have termed plasma therapy as 'outdated' and the Indian Council of Medical Research (ICMR) had also claimed that plasma therapy does not reduce the number of deaths associated with COVID-19.BENGALURU: HCG Hospital the first healthcare facility in the state to provide convalescent plasma therapy for Covid patients last year — has recommenced the treatment as there has been a spike in cases over the last few days. Last year, when cases were increasing, HCG stared plasma therapy under the guidance of Dr Vishal Rao. It gradually petered out as cases reduced in December and requests for plasma donations Stopped coming from January this year. But with the second wave on in the state, the hospital has started receiving 4-5 requests per day and it has decided to restart the treatment. There were two important learnings from plasma therapy last year. One, to check if the donor has high antibodies before donating plasma, and the other, giving plasma early when the patient is breathless and not wait till the situation deteriorates. Plasma therapy should be given when the patients are moderate-to-severely ill, and not when they are critical. On ICMR's phase-3 plasma trials data, which stated that plasma therapy did not help, Dr Rao said the biggest critique of their study was that they did not check antibody levels of the donor and that their donors were all asymptomatic patients. He also said that plasma therapy worked in Karnataka as vitros antibody assay was carried out to check antibody levels, before taking plasma from the donor. The 'Solidarity Trial' conducted by WHO in 30 countries from March 2020 at 405 hospitals; 11330 adults underwent randomization; 2750 were assigned to receive Remdesivir. The interim results of the 'WHO Solidarity trial' published on December .2020 showed that Remdesivir had little or no effect on hospitalized patients with COVID-19, as indicated by overall mortality, initiation of ventilation, and duration of hospital stay by **Advisory for Rational use of Remdesivir for COVID-19 Treatment MOHFW, AIIMS and ICMR** have jointly issued treatment guidelines for management of Covid19 patients.

B. Tocilizumab in COVID-19:

some clarity amid controversy Hyperactivation of the immune response, including release of pro-inflammatory cytokines such as interleukin-6 (IL-6), might play a key role in the pathophysiology of severe illness from COVID-19.1 Consistent with this notion, one of the few therapies that reduces mortality in hospitalised patients with COVID-19 is the corticosteroid, dexamethasone. Accordingly, there has been great interest in examining whether treatment with additional, more targeted anti inflammatory agents beyond steroids could provide further benefit. Tocilizumab is a recombinant humanised monoclonal antibody that inhibits binding of IL-6 to both membrane and soluble IL-6 receptors. Early observations from China suggested improved outcomes in hospitalised patients with COVID-19 who received tocilizumab.3 These preliminary reports were followed by large observational studies in

critically ill patients with COVID-19, which suggested a mortality benefit with tocilizumab.

C. Uses of 2DG IN COVID PATIENTS: -

The Defence Research and Development Organisation (DRDO) on Tuesday said its anti Covid drug, **2-deoxy-D-glucose or 2-DG,** can be given to patients under the care and prescription of doctors as it issued directions for its use. "Ideally, 2DG should be prescribed as early as possible by doctors for moderate to severe COVID patients for a maximum duration of up to 10 days," DRDO said.

Definition of Covid-19 Death:-COVID-19 deaths were defined as any death within 28 days of a positive SARS-CoV-2 test.

Materials & Methods:-A retrospective randomized control study was done on the selected sample of 100 COVID -19+, who were admitted at Nalanda Medical College and Hospital Agamkuan, Patna, a fully dedicated hospital for COVID -19+ patients. Patient's age was between 15- 80 years and the duration was this study from 01-03-2021 to 16-06-2021.

Methods of Collection of Data:-Using simple lottery random method 100 samples were selected. From these 100 patients, 50 patients were randomly assigned to case group and 50 patients in control group after informed consents of relative obtained. Patients in the case group who being died after got COVID-19+ whereas 50 patients in the control group participated who were survive after got infected from COVID-19+ patients.

Inclusion Criteria:-Those Patients Who Were:-

- Admitted At Nmch, Patna.
- Male & Female Both Were Selected For This Study.
- Vaccinated.
- Death & Survive After Getting Covid-19+.
- Relatives Giving Consent to Participate In This Study.

Exclusive Criteria:- Patiets Who Were:-

- <15 Years – 80 Years Of Age.
- Not Admitted At Nmch, Patna.
- Pregnant & Lactating Mothers Were Not Allowed For The Study.
- Non-Vaccinated.

RESULTS

For the description part of analysis of statistical data there were 100 patients were randomly selected who were admitted at NMCH, Patna Bihar. There was two groups **(a)** Case group with 50 death patients from the COVID-19+. **(b)** Control group with 50 survival patients from covid - 19 + and the result of the study analysis was based on the three variables i.e. **1.**Vaccination status.**2.** Severity of disease which classified into three groups such as mild, moderate and severe.

A. **Mild: -** Those patients who were on simple face mask.
B. **Moderate: -** patients who were on the NRBM.
C. **Severe: -** such kind of patients who were on the BiPAP.

Last category was outcome which has two sub categories like death and survival.**(a)Vaccination status:-**For the vaccination status we have seen 59 patients were not vaccinated & 41 patients was vaccinated out of 100. **(b)Incidence: -** There were 41% patients were vaccinated whereas 59% patients were not vaccinated.**(c)Severity: -** In the case of mortality we selected 50 patients who were died from the Corona and I got to know that out of 50 patients there were 12 (24%) patients were vaccinated whereas 38 (76%) patients were non-vaccinated. Although for the 50 control survival group total 29(58%) patients were vaccinated and 21(42%) patients was not vaccinated all graph start.

Table 1 Contingency table provides the information the observed cell totals (the expected cell totals) and [the chi-square statistics for each cells]

N=100			
	DEATH	**SURVIVAL**	***Marginal Row Totals***
Vaccinated	12 (20.5) [3.52]	29 (20.5) [3.52]	41
Non vaccinated	38 (29.5) [2.45]	21 (29.5) [2.45]	59
Marginal Column Totals	50	50	100 (Grand Total)

Chi-square =11.94
p.value = .000547
Significant at p<.05

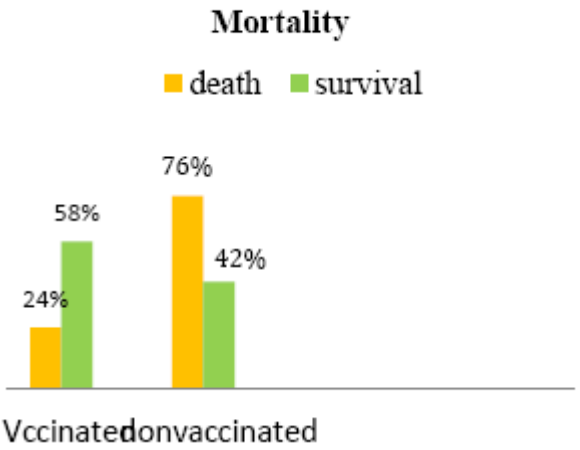

Fig.1.Column chart showing the distribution of participants according to their death and survival.

Table 2 Contingency table provides the information the observed cell totals (the expected cell totals) and [the chi-square statistics for each cells]. N=100

	Moderate Covid19	Severe Covid 19	*Marginal Row Totals*
Vaccinated	32(20.5) [6.45]	9(20.5) [6.45]	41
Non vaccinated	18(29.5) [4.48]	41(29.5) [4.48]	59
Marginal Column Totals	50	50	100 (Grand Total)

Chi-squre=21.0685
p-value=<.00001
Significant at p<.05

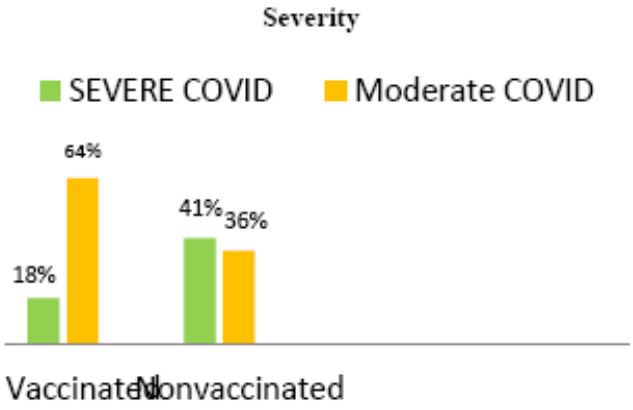

Fig.2.Column chart showing the distribution of participants according to their moderate and severe covid-19+.

Discussion:- Since its emergence in December 2019, SARS-Co-2, the virus that causes corona virus disease 2019 (COVID-19), has taken a tremendous toll globally; by 28 February 2021, there have been over 110 million cases and 2.5 million deaths worldwide from COVID-19 *(1)*. Although most COVID-19 deaths occur among older adults and persons with chronic co-morbid medical conditions, deaths have occurred in persons of all ages. Moreover, the pandemic has caused widespread morbidity and necessitated control measures that have devastated economies worldwide. In response to the pandemic, the global efforts to develop multiple vaccines to protect against COVID-19 disease have been unrivalled in the history of public health. By the end of 2020, two COVID-19. vaccines have received emergency use approval. By maturity level 4 regulatory authorities, based on reaching predefined criteria for safety and efficacy,and at least several dozen more are in clinical trials. From December 2020, vaccines started to be rolled out according to various allocation plans, which differ by country. Generally, these are based on criteria of risk of serious disease and death, ethical principles of fairness and equity, and considerations for restarting stalled economies. As vaccine production capacity scales up and new products are authorized, allocation criteria will broaden until supply enables widespread use of vaccines.

During the initial implementation phases, as for every new vaccine, post-introduction evaluations will be important to address many of the remaining questions about the performance of these vaccines. When a vaccine is used outside trial populations the effects of the vaccine may differ in specific geographies or

subpopulations. Vaccine effectiveness (VE) might be different against various disease outcomes, against infection and infectiousness, and against newly emerging virus variant strains. Additionally, important programmatic issues will need to be addressed, such as the effectiveness of incomplete dose schedules, variation in dose intervals, and the interchange ability of different vaccine products. Suboptimal cold

chain capacity, and off-schedule and incomplete delivery of doses could lead to different vaccine performance. Vaccines might not be as effective against new variants. Finally, assessing the duration of vaccine protection requires longer term studies. **Robert M. Kaplan and Arnold Milstein (January 21, 2021),** Influence of a COVID-19 vaccine's effectiveness and safety profile on vaccination acceptance, Although a safe and effective vaccine holds the greatest promise for resolving the COVID-19 pandemic, hesitancy to accept vaccines remains common. To explore vaccine acceptance decisions, we conducted a national survey of 1,000 people from all US states in August of 2020 and a replication in December of 2020. Using a 3 × 3 × 3 factorial experimental design, we estimated the impact of three factors: probability of 1) protection against COVID-19, 2) minor side effects, and 3) a serious adverse reactions. The outcome was respondents' reported likelihood of receiving a vaccine for the coronavirus. Probability of vaccine efficacy (50%, 70%, or 90%) had the largest effect among the three factors. The probability of minor side effects (50%, 75%, 90%) including fever and sore arm, did not significantly influence likelihood of receiving the vaccine. The chances of a serious adverse reaction, such as temporary or permanent paralysis, had a small but significant effect. A serious adverse reaction rate of 1/100,000 was more likely to discourage vaccine use in comparison to rates of 1/million or 1/100 million. All interactions between the factors were not significant. A replication following the announcement that vaccines were 95% effective showed small, but significant increases in the likelihood of taking a vaccine. The main effects and interactions in the model remained unchanged. Expected benefit was more influential in respondents' decision making than expected side effects. The absence of interaction effects suggests that respondents consider the side effects and benefits independently.

Importantly, we do not recommend that COVID-19 VE evaluations be conducted by all countries introducing COVID-19 vaccines.

Vaccine evaluations will likely be conducted by a number of countries worldwide, for a variety of different vaccines, and the results can be expected to be applicable to other countries in the same region with similar populations, COVID-19 epidemiology and immunization systems.

SUMMARY:

- Mean age of the infected patients was 51.9 years whereas standard deviation (SD) was 14.84.
- Mean of duration of stay of the patients it was 11.01 although SD was 8.707.
- In this study there were total 100 COVID-19+ patients were selected for the study.
- They were randomly assigned in the case group as well as control group and each group had 50, 50 particiapnts.
- Those covid-19+ patients who were vaccinated and not vaccinated.
- Clinical and demographic variable between two groups were compared it was statistical significant.

LIMITATIONS:

- Sample size was very small.
- Require large sample size ,especially if outcome of interest is uncommon such severe covid -19
- Vaccination status was difficult to determine in retrospective study without good vaccination records.

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