

Efficacy and Safety of COVID-19 Vaccine

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ABSTRACT

Background: COVID-19 is the emerging global medical emergency which has severely plagued the whole world. Large scale immunization program has already been started and it needs to be accelerated. Various types of vaccines such as messenger RNA vaccine, viral vector vaccine, protein subunit vaccines are being manufactured after emergency use authorization all across the world. These vaccine candidates need to be efficient and the reactogenicity must be as low as possible. The efficacy of the vaccine must be high and cohort of the studied patient should consist maximum number of subjects to get better results. As far now, all the vaccine candidates have shown good efficacy, but the mutation challenge is haunting as mutant variants can evade the vaccine protection. Preventive measures are one of the most effective measures available and which are time tested. Vaccines are one of the preventive measure and its various candidates have been granted emergency use authorization by the drug controlling agencies all round the world. More study needs to be done in order to solidify the efficacy results of the vaccine. The waning of the immunity post inoculation is one of the important needs to be studied as the worldwide debate on the booster dose has already been started.

Key words: COVID-19, Novavax, Vaccine, Immunity, Inoculation

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INTRODUCTION

COVID-19 is the evolving pandemic that has originated in the Wuhan city of the Hubei province in China. Since its inception, the spread of the disease has been unprecedented and other disease in the recent history was so notorious for crating the havoc of the global scale. Till January 27, 2022, 362,541,740 case of COVID-19 infections have been reported entirety throughout the realm of planet earth [1,2]. Unfortunately, 5,626,906 people reportedly lost their lives to the COVID-19. Strict measures were taken in the initial days of the pandemic [3]. Doctors were not allowed to keep patient in open and they should be in quarantine as the disease is highly contagious. No engagement is permitted with the patient as the COVID-19 is highly communicable. Health care authorities have to don the Personal and Protective Equipment's (PPE) kits round the clock so that the folks don't contract illness. Because of extended segregation among severe patients, psychosomatic anxiety is stimulated in the patient as they are inept to see their relatives. Furthermore, there is commonness of post traumatic distress syndrome which occurs to the patient

due to near death encounter. The indecision about the COVID-19 pandemic is by this time prevalent amongst overall masses and one and all are concerned regarding their forth coming projections. Health care professionals on the opposing have to toil over time to serve the inflow of the patients suffering from COVID-19. The stretched hauls in PPE kits turn into one fatigued and jaded. Similarly, the concealed fright of diffusing the illness to their kind red and loved ones override their mental stage and efficacy of the same is impacted. The inner impact is often below analysed where as its associations with other facets of human life is quite cozy and also it can distress the corporeal working of the body [4].

The huge figures of case mortalities which are reported from all over the globe also somewhat saddens the temperament and intensifies the hesitation about the current condition. Preventive measures are one of the most effective measures available and which are time tested. Vaccines are one of the preventive measure and its various candidates have been granted emergency use authorization by the drug controlling agencies all round the world. Mutation in the virus is grave reason of apprehension as it can allegedly evade the immunity protection of the body. Genome sequencing is necessary and it can offer new data to rectify the efforts which are used to curbing the spread of the pandemic. Fewer than 18 populations have also been started to be inoculated as they are the major chunk of the population [5].

LITERATURE REVIEW

Pathophysiology of COVID-19

Coronavirus disease 2019 or COVID-19 is the emerging lethal illness infection which has no end to its menace in near line of sight. It is extremely important to understand thoroughly, the pathophysiology of the COVID-19, so as to successfully curbing the spread of the disease. COVID-19 is affected by the novel Coronavirus which is the member of the Coronaviridae family which has previous outbreaks of SARS and MERS. This structure of the virus makes it to be called as Coronavirus because of its crown shaped structure. The detection of the novel Coronavirus was way back in the December of 2019 but it is still persisting after more than two years has been passed since its inception. The virus is not controlled and is still evasive from the preventive measure. The exceedingly transmissible kind of the viral strain and ability of the novel Coronavirus to make the unmanageable clinical complications are factors behind the invincible nature of the virus [6].

Successive waves have proved extremely fatal and millions of people lost their lives to the manifestation of the COVID-19 which is quite complicated. The spike protein on the virus gets attached to the Angiotensin Converting Enzyme 2 (ACE 2) receptors which act as the getaway for the virus. The ACE 2 receptors are expressed extensively on the most vital organs and organ systems of the human body. The access makes the virus bold and the organs are prone to the direct attack of the virus. Meanwhile the primary pathway of the virus is the respiratory pathway which is very prone to the viral infection. Bodily openings like nose, mouth and eyes are some of the entry points for the virus to gain access to the internal structure of the human body. The upper and lower respiratory tracts are the primary target while it can rapidly proliferate to the lungs and alveolar tissues of the lungs. The pulmonary damage is the key reason behind the occurrence of acute respiratory distress syndrome which is quite difficult to manage. In fact, ARDS is the single most unmanageable clinical manifestation which is becoming the cause of concern as more and more patients are being experiencing such life threatening condition. The incubation periods of the virus are approximately ranges from 4 to 12 days and after 5 days, the symptoms starting to take forms. Some patient might vary from the above stated inference. The symptoms are wide ranging and have variety of consequences on the human body [7]. The most common symptoms include cough, cold and fever along with loss of taste and smell. More severe symptoms include dyspnoea, ARDS, diarrhoea, pan body inflammation and so on. The categorization of the symptoms helps to divide the response into various grades to optimize the viable resources. As the health care infrastructure was completely collapsed under the immense pressure of the influx of the patients of COVID-19, it was important to judiciously use the remaining and available resources so the approach can be streamlined in the efficient way. Although the case fatality rate may seem lower than the

previous outbreaks of SARS and MERS, but the actual translation of the rate into number of patient deceased is extremely high. In excess of five million individuals suffer the loss of their lives owed to the difficulties affected by COVID-19. So it is extremely necessary to identify the disease infection at the earliest so that the patient can be treated in the sufficient window of the time. Previous outbreaks of SARS and MERS have some valuable lessons to offer as it can shed light on the effective way to control the spreading pandemic. Although the spread of both the previous outbreaks were confined to certain geographical boundaries [8].

The main hurdle in containing the pandemic of COVID-19 is its highly transmissible nature. Moreover, viruses exhibit one more lethal property and that is mutation in their structure. Mutation in viruses is a very common phenomenon and most of the mutations are of minor nature, but certain major mutations can alter the whole behaviour of the virus and thus it becomes more difficult to predict the trajectory of the virus's manifestation. There are two types' approaches to tackle the menace of COVID-19. One is the post infection approach that is curative treatment approach which is being widely followed and another is preventive approach which is based on the theory of preventing the disease infection from happening at first place [9].

DISCUSSION

Want of curative approach than preventive one

Coronavirus disease 2019 or COVID-19 is the unanticipated medical calamity that has been stretch all over the populated locations on globe. Each and every dweller of the planet Earth has been shaking by COVID-19 pandemic by one way or the other in most instances that is in undesirable way. In excess of hundred million inhabitants have been affected by the infection which is an unprecedented and calamitous incident in itself. In nearly previous 100 years of the antiquity of human society, no such occasion was so effective in producing such extensive annihilations billions of people in one knock. More than five million people have lost their lives owed to the clinical difficulties shaped by COVID-19 [10]. Such obliteration forced the academics and observers to term it as once in a 100 years' occurrence which underlines its critical aftermaths. The medicinal predicament has also climaxed into socioeconomic crisis as numerous Non-Pharmacological Interventions (NPI) has encouraged steps such as lockdown and movement restrictions which left huge number of people without jobs. The wretchedness of not even receiving passable quantity of food and other essential supplies were not met in latest bygone of the human civilizational antiquity. The newness of the Coronavirus only adding to the afflictions as there is no time honoured medication therapy accessible to check the viral extent of the COVID-19 pandemic. The upkeep of ad hoc therapy is what supporting the fight against COVID-19 to definite point. There is no global north south division amongst the infection cases and fatalities

and all the advanced and evolving nations are distressed on equal gauge. This was conspicuously sensed when extremely high cases of mortalities were registered on daily basis during the early time from economically affluent nations such as Italy and Spain. Hence there was no bias displayed by the novel Coronavirus amongst rich and developing nations and it has negatively impacted all the inhabitants. The social and economic impression too is so serious that comprehensive assessment of such factor would conclude extensive damages [11].

The health bearing has been deliberated all over the planet and there is little to no encouragement in becoming infected with the novel Coronavirus virus. The crumbling health care system, dearth of proficient therapeutic specialists, deficiency of state of the art medical gear's is the indication that the health care system as an entire was flabbergasted and is not planned to satisfy such abrupt and massive request of patient shaped by COVID-19. The therapy of the viral infection is not yet approved by health care authorities [12]. Moreover, medical sicknesses lying beneath which are otherwise known as comorbidity is the chief decider in course of COVID-19 infection about the harshness of the clinical indications. The comorbid sufferers have elevated chance in increasing ruthless clinical symptoms and the lethal outcome results in patient if condition worsens. Distant from adversities for the duration of the therapy segment, there is novel observable fact called as long COVID-19 condition in which the infection troubles the affected patients post recovering from the aforementioned disease too. Numerous patients from all over the Earth have seemingly nit picking about the less elucidated trend also known as continuance of symptoms. Many indications of COVID-19 have been apparently troubling the patients even after the healing phase. Symptoms such as fatigue, cough, cold and fever, intermittent loss of taste and smell, brain fogging which is the disorder of misperception while get to any judgements, lessening of bodily ability and so on continued amongst particular segment of patients even after the salvage. Furthermore, afterward *via* medicinal scrutiny of the patient numerous inner damages came to notice which is also a grave reason of apprehension. It ascertains that novel Coronavirus causing COVID-19 can bring about irreversible harm to the concerned person.

Numerous examinations revealed that there was deterioration of cardiac muscles, lessening in muscular ability, lessened supply of blood to cardiovascular system like heart, myocarditis, reduced circulation level of O₂ and CO₂, wearying of alveolar tissue, kidney and hepatic damage are certain of the conclusions which arose from the ailing sufferers.

Types of COVID-19 vaccines and its efficacy

Certain types of vaccines which are used in any infectious disease outbreak to control the spread. This categorization is on the bias of the function of the vaccine and its working mechanism. There are broadly three types of vaccines of COVID-19 which are now available for the mass immunization program. These are vector

vaccines, mRNA vaccine and protein subunit vaccine. Vector vaccines are one of the most common vaccines available and are prepared by injecting the dead or weakened strain of the novel coronavirus. Once injected the body reacts to it as the live virus and signals all the cells to make necessary antibodies to fight out the infection. As the virus is dead and weakened, there is extremely less to no chance of being infected by the virus. These types of vaccines provide immunity cover and hence, successive infections are easily bore by the vaccinated person. Messenger RNA or mRNA vaccines work by injecting the information about the virus. The RNA then does not enter the nucleus and it is sufficiently workable vaccine. The protein subunit type of vaccine only takes into account the most triggering part of the virus which can stimulate the immune system to maximum extent [13].

Several studies have been done in order to prove the efficacy and workability of the vaccine on the COVID-19 infection. Without proper study and evaluation, the approval of the vaccine candidate is highly unlikely. One study done on messenger RNA type vaccine of COVID-19 termed as mRNA1273. A pool of 30420 volunteering subjects was studied *via* administering vaccine and placebo on one is to one basis meaning, half of the subjects were administered the original jab and rest were inoculated with placebo. The primary aim of the study to study the viral behaviour among the subjects administered with vaccine. 7923 males and 7258 females were administered the messenger RNA vaccine which stood the percentage of both the sexes at 52.2 and 47.8 respectively. These trials were randomized and placebo blinded trails in order to take out the highest accurate data. The messenger RNA type vaccine showed the efficacy of 94% which is quite impressive. The assessment was done after two weeks for checking clinical manifestation ad symptoms of COVID-19. 30 subjects showed severe symptoms and one of them met with fatal clinical outcome. The vaccine was found to be effective in preventing the onset of critical symptoms which is caused due to COVID-19 infection [14].

The Ad26.COV2.S vaccine is a recombinant, imitation incapable human adenovirus type 26 vector. The study is necessary which must be of randomized control trials. In these vaccine trials, 19630 subjects were studied after administering the placebo as well as jab in one is to one proportion. The observation was done on after 14 and 28 days after the illness. The efficacy of the aforementioned vaccine was seen high among the older population than the younger ones. But taken into consideration of other non-pharmacological interventions like wearing of masks and maintain physical distancing along with sanitization at regular intervals. The vaccine efficacy stood at 93.1% which is good. It was found that only a single dose was effective against the severe and critical symptoms of COVID-19 which are the main cause of case fatalities worldwide [15].

Now many vaccine candidates for the population lesser in age than 18 years have been approved and it also had shown some positive results. Major chunk of the world

population was left out of the vaccination campaign and through these types of vaccines, this section could be immunizing as early as possible. One such study indicates the efficacy results of the BNT162b2 COVID-19 Vaccine in Adolescents. The age group examined and studies were 12 to 15 years of adolescents. Overall 2260 teenagers were part of the immunization study and its efficacy. Placebo, blinded randomized controlled trials administer the jabs of BNT162b2 to 1131 subjects and 1129 were administered a placebo shot. The vaccine was checked for any adverse reaction or the rejection by the human body. No COVID-19 cases were observed after the onset of 7 or more days which bringing its efficacy to 100% among adolescents. Whereas there were 16 cases registered of COVID-19 among placebo group.

Another vaccine candidate, NVX-CoV2373 vaccine (Novara), was studied in the same way as previously randomized control trials were organized. In these cohorts, 15187 participants noted their part. Almost 30% of the population was above 65 years of age as these are the extremely vulnerable population which most of the time present critical symptoms post COVID-19 infection and consists of major chunk of the case fatalities that is happening due to COVID-19 related complications. The reactogenicity was transient and also mild in nature. The efficacy stood at 89.7%. The infamous variant of concern, B.1.1.7, WAS ALSO being inhibited to manifests into the human body after the inoculation of NVX-CoV2 373 vaccine (Novavax) [13].

Concern regarding persisting mutation

Mutations in the virus are extremely common and few are the major mutations which are a serious cause of concern. Mutation not only alters the over structure of the virus; It also impairs the viral behaviour in more adverse way [16]. Viruses are quasi living organism and they need host to survive and reproduce. Moreover, to protect themselves from the antibodies produced by the human body or any host body, they need to make several changes in their spike proteins so that their unhindered access to the inside of the cell remains intact. Vaccines have so far shown considerable amount of protection against the viral behaviours. But certain mutations have been found to be evading the immunity provided by the vaccines. Moreover, the waning of the immunity is also a serious cause of concern as it can easily have exploited by the constantly evolving virus. In fact, mutation is the prime reason behind the long stay of the virus ad still there is no end in line of sight of the virus's nuisance activities [17].

CONCLUSION

The exceedingly infectious character of the latest entrant of the Coronaviridae family of viruses coerces the medics and health care professionals to stick to segregation and seclusion set of rules in which the infected person is held in reserve sequestered from entire the uninfected family members. The entire randomized controlled trials AE showing promising results. These vaccines candidates are getting emergency use authorization because of the

dearth of vaccines all around the world. This has cause the fluting of some norms as rigorous trials are needed to get approvals from the drug controlling agencies. Constant monitoring of the cohort is necessary to obtain a pool of data which is comprehensive and which can be useful in designing the path of resistance against COVID-19 pandemic. Vaccines are the only viable and feasible option available that is effective against the COVID-19. Immunization must be accelerated I all parts of the world and no part of the globe must be left behind in order to successfully curb the spread. As even one person is left behind by any chance, it has the potential to again stall the whole world as it as seen in the initial periods of the COVID-19 pandemic.

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