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Review Article

Passive Immunotherapy Using Approved Vaccines for the Management the Evolving Fast Spreading SARS Cov-2 Variants: A Personal Viewpoint from the UK Perspectives

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ABSTRACT

The current use of the IT tools, so called, Artificial Intelligence in the procedural, patterns and large data analyses have proven to be extremely useful in establishing some newer generation of drug therapy. This manuscript aimed to provide an update on the current status of passive immunotherapy, using the two currently approved vaccines that appear to provide a balance amount of CoV-2 neutralizing antibodies, after 3-4 weeks to individuals in need for either preventative or therapeutic intervention.

Keywords: COVID; SARS CoV-2 variants; RNA; immune system; Vaccine therapy

INTRODUCTION

The development/deployment of vaccines and the related therapeutic modalities for the management of COVID infection [1-3]. No wonder, since WHO announce Coronavirus pandemic, many investigators have switched their research development studies to better understand the role played by various mode of immunotherapies including the coronavirus convalescent plasma [CCP] and the vaccine-induced neutralizing antibodies for the prevention and management of various abnormalities associated with the Coronavirus acute respiratory diseases, as highlighted previously as the work in progress [4-10]. Clearly the 2021 is considered to be testing times for many of us, as CoV-2 with its evolving variants, is outwitting all us and we must remain vigilante and committed to support both our community and the health care systems, by all possible means, to reduce the rate of this fast spreading infection and to save some lives.

Attempts are made, in particular, exploring the values of one single dose [instead of the two shots] protocol that has being recently introduced in the UK to overcome the shortage of vaccines delivery and distribution. The good news are: Firstly the UK Government took the boldest mass vaccination program, by creating some groups of volunteers, helping in the sprit of oneness, in speedy effective mass vaccination scheme, a true UK-wide national efforts to cheer all us even in the Valentines' day as in 68 days 60 million jabs are given to most four high priority vulnerable populations that constitute 80%-90% of death from Coronavirus. Secondly the preliminary data gathered so far indicate that even the first dose of two types of the given vaccines, have achieved 67% effectiveness and the infection rate is coming down rapidly by combination of vaccine therapy with partial lock down strategy. Nevertheless, long covid with mild and moderate symptoms appear to be not affected by these vaccines and we must focus on targeting the most virulent CoV-2 variants and vaccines for children that are the topics of the current focus. Moreover we should not drop our guard too early and be guided by data and working on the best operational and clinical strategies, rather than just pure optimism by lifting too soon the restriction and going only cautiously and sensibly to survive as beating COVID will be an impossible task as there is a seriousness in the current number of death and number of hospitalization and we must at least keep school staffs vaccinated and children apart as an urgent plans of action, as new school terms are starting soon.

Fortunately new vaccines involving also N protein in addition to spike protein is developing with the hope of enhancing higher levels of antibodies generation and immune T-cell responses. Moreover newer vaccines to other genetically mutated are progressing to optimize the current state of the art of targeting the newer variants that we are doubtful the existing virus will be sufficiently effective. Moreover it should be noted while vaccines are bringing slowly the hospitalization levels down but not yet fully effective to reduce the transmission rate of the infection, in particular in view of fast spreading variants. Hence international collaborative efforts are required to tame infection, even with creating the requirement for travel passport and plenty of other travel restrictions as the race between targeted vaccine development and deployment using some modern and effective armatures must remain on agenda to survive

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the rate of viral mutation, until we bring down fully the rate of this infection with the expected human ingenuity.

THE CURRENT POSITION OF VACCINES DEPLOYMENT IN THE UK

In the context of where we are now and where we are going, while globally 9 candidate vaccines are in various stages of phase III safety/efficacy trials for approval, as described by this author previously nine but only two well established manufacturers [Pfizer and AstraZenika] have shown the capability to deal with the enormous demands, in view of the pandemic nature of this infection, as the shortage of the vaccines remains as the bottleneck of mass vaccination. This is of particular relevance, as AstraZenika had no choice that cut even the promised supply timely, which created enormous problematic concerns, in particular in European countries that were too slow in securing their supply well in advance as the UK and USA. On the other hands Pfizer like some other producers, come to special deals to provide large scale supply to some countries, if they could get access the results as a joint venture, for example the mass vaccination with the greatest success in Israel and the planned Novavax, protein based vaccine, in Australia, etc. [9]. Moreover the evolving SARS CoV-2 variants, that spreading much faster than the original strains also enhanced the need for massive vaccination. In this context we explored where we are, in respect of using the two doses messenger RNA of the spike proteins as produced by Pfizer/BioNTeck well-established protocol and then the Oxford/AstraZenika' vaccine, based on Adenovirus technology but in the context of the current UK strategy, for delaying the second dose delivery of both vaccines from 3 weeks to 3 months delivery scheme, to make the existing available vaccine supply to larger numbers of the four high priority groups.

CONCEPTUAL ACCEPTANCE OF SINGLE JAB STRATEGY

It is noteworthy to highlight that the single jab strategy has never been tried before and also overriding the Pfizer approval protocol of 3-4 weeks, but the WHO recently approved this protocol for the oxford vaccine, despite previously recommending an intermediate duration up to 6 weeks interval for the Pfizer vaccine, on the basis the best available evidence. However, in support of the UK decision it should be mentioned that the one dose of Pfizer/Biotech's COVID-19 vaccine is 51% effective at preventing both symptomatic and asymptomatic SARS-CoV-2 infection and this level of efficacy meets the WHO acceptance criteria for the useful vaccine to be equal or over 50% efficacy. This concept is also supported by a new trial on Moderna' vaccine, using the same vaccination principle, than the Pfizer vaccine, indicating that that a single dose is effective after 2 months of vaccination. Hence single jab strategy based on available data could allow us to pursue with a greater speed the global mass vaccination programed in the UK, later in the year, though at least 5 types vaccines that becoming available later[potentially in late April-June] that al including the Moderna , Novavax and even Johnson and Johnson, based of single dose principle, all under current evaluation by the UK as the global collaborative efforts despite these vaccines having some differing characteristic property in design and applications, as in the Moderna technology the mRNA of the spike proteins is encapsulated in a lipid capsule facilitating its storage and distribution at -20 freezer, in contrast to the Pfizer technology the vaccines need to be stored and transported at ultra cold well below-70, making it operationally more difficult in some country with poorer infrastructures and the Oxford vaccine only required storage in cold room or fridges, making it operationally simpler to control with reliability. The detail characteristic properties of other candidate vaccines are highlighted before [9]. Nevertheless, it should be point out that need for the second dose, as booster to optimize duration of their effectiveness with reliability and consistency cannot be denied. Moreover, evidence is accumulating on the effectiveness of these vaccines for all ages, including over 65 and these have been now supported by the recent findings both in the most successful Israelis study with the Pfizer vaccine; the US studies on both Pfizer and Moderna vaccines and the Oxford-AstraZenika clinical trials data, on all aged group, that led to its approval. Needless to highlight that the timely production distribution of such an important biologically fragile vaccines, requiring in depth quality control for the release and supply of the final product remains one of the major obstacle hence considerable efforts are directed in developing other types of vaccines internationally for self-sufficiency and some reaching to large-scale production and distribution of all types of newer vaccines under development [9].

CURRENT CONCERNS IN DELAYING THE SECOND JABS

The delay the second vaccine dose for all the approved vaccines is becoming as a matter of concerns in regard to optimization of the immunity in individuals who have been vaccinated or has been exposed the virus and have already some measurable levels of high affinity antibodies in circulation. This is of particular relevance as the standard used in the various manufacturer's trials on vaccines, was based on the relative values on the level of antibodies seen in the convalescent plasma, at the time of studies, hence enhanced levels neutralizing antibodies remains to be clarified in line with the current opinions:

Whether one or two doses of vaccine are required in people who have already been infected with SARS-CoV-2?

a) As the one shot is probably sufficient, as there is some level of antibodies against the virus exist in people who were already infected and with one shot, they basically develop the level of antibodies that most people get with two shots of vaccine; b) Is the infection has primed the immune system and the one shot vaccine is effectively boosting those existing immune responses? It is clear that immunologically, infection generates immune responses, (not just B-cell but also T-cell memory response), and some level of immunity but again there is enormous recipients' variability, but just one shot of vaccines or exposure to infection would be boosting immune responses to the point where they have antibody levels that physiologically are considered to be optimal for protection. Even if you had mild disease such asymptomatic infection, just one shot appears to be able to bring the antibody levels up high enough to protect them against reinfection without vaccination; c) Do we need to correlate of protection against what antibody level is required as some people will cross the threshold of antibodies needed for protection right from start, with high efficacy vaccine and others who already had COVID might have more pronounced reactions to the second vaccine dose? This will be rather worrying, particularly in view of the very narrow window of time in between the first and second shots that if they are making a robust antibody response, the second shot might result in an even stronger reaction; d) would these booster shots be advisable for people who have recovered from COVID? In fact, some vaccine companies are currently thinking about giving a third

shot in an effort to boost immune responses and address the virus variants that are circulating, which is something that will need to be considered carefully for people who have already had COVID. Perhaps it would make sense to wait 3 months to get the booster if their antibody levels are waning; e) Given the limited vaccine supply, would it make more sense from a public health perspective to instead allocate these second doses to vaccinate more people? Hence, we could conserve that second dose and give it to people who really need it or using as vaccine boosters to address the viral variants, against which some existing vaccines seem to be slightly less effective requiring more 10 times antibodies to be effective.

FUTURE PERSPECTIVES

Clearly the deployment of existing COVID-19 vaccines, and the ways to optimize distribution of limited supply, the viral loads of some variants that continue to spread globally, and new approaches to vaccination that may offer protection more broadly against existing and emerging coronaviruses remains full of uncertainly and rising some pertinent questions that remain to be answered, despite numerous positive news in the pipeline:

a) A single dose of COVID-19 vaccine in healthcare workers who have already been infected with SARS-CoV-2 provides evidence that antibody responses to the first vaccine dose in individuals with pre-existing immunity to SARS-CoV-2 is either equivalent to or better than that found in individuals who receive two doses of vaccine;

b) The B.1.1.7 SARS-CoV-2 variant that was first identified in the UK is of major concern for existing COVID-19 vaccines as this variant while is more transmissible, but it may also cause more severe disease however new trials on the approved Modern's mRNA vaccine demonstrates reduced but still substantial neutralization of the B.1.351 SARS-CoV-2 variant that was first identified in South Africa;

c) Nanoparticle technologies in developing vaccines that can protect against multiple strains of coronavirus and this could be a potential strategy to protecting against SARS-CoV-2 variant strains and other emerging zoonotic coronaviruses;

d) Meanwhile some studies are in progress examining how the timing of the booster dose of the AstraZenika vaccine impacts its efficacy.

CONCLUSION

To sum up while the debate on the values of one versus two shot continues, despite the great success of the Israeli studies on over 55 old using two shots Pfizer vaccine and in view of the great number of uncertainties on the one shot protocol, we need to prioritize the balancing act between the speed of more dangerous viral development and the rate of global vaccination in this pandemic. Even considering that the current vaccines will be successful, we are still in need of more tools and novel approaches to effectively fight back the evolving SARS-CoV-2 variants contagion, by teaming up with prominent scientists and institutions from around the world to help find novel ways to protect people from SARS-CoV-2 infective attacks.

One of the ground breaking methods to prevent COVID-19 infection is using neutralizing polyclonal antibodies against the existing and emerging SARS-CoV-2 variants emerging SARS-CoV-2 variants [such as the fast spreading Kent-UK and the young South African strains] that can easily be obtained from some CCP mini-pool or from successfully vaccinated mini pool of some good responders, to directly protect as a first line of defence against COVID.

The many advantages of this approach include to obtain purified neutralizing antibody concentrate by affinity adoption column from the above mentioned mini pool free from the potentially infection-induced various abnormalities, autoantibodies, residual viral infection and cytokines hence rapidly support the mass vaccination as a passive immunotherapy to catch the virus before it enters or exits the body by immobilizing SARS-CoV-2 and inhibiting viral binding to the ACE-2 receptor. This approach has been successfully used for immunotherapies to fight Influenza, and Ebola crises as the active therapeutic agents. The proven versatility of the immunotherapies offers interesting new opportunities as a method to prevent infections. The beauty of such a hyper concentrate is that they are obtained from a mini pool from the real time covering all variants with some superior properties such as chemical stability, high affinity to a broad spectrum of epitopes, low immunogenicity, the ease of production and being promptly effective in an infection relevant SARS-CoV-2 virus model as compared to Vaccine therapy to generate high levels of antibody in 3-4 weeks in good responders.

Nevertheless we must always take into consideration crises and chaos observed in mental health and the socio-economic and in the physical wellbeing of the life that we are used too. Hence it remains essential that we comply closely and adhere to all restriction without dropping our guard to early as this virus leaned to mutate to escape our current mode of protective, in particular if given some chance to develop more dangerous variants without some continual surveillance and perseverance to stop its fast growth. These remind us again to recalibrate our thinking about how to approach the pandemic virus and shift our focus from the goal of herd immunity against transmission to the protection of all at risk individuals in population against severe disease that is the global aim of the AstraZenika virus of the world.

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