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Short Communication

Expanding the Role of Monoclonal Antibody Therapy in COVID-19 Infections

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Quotation

"Monoclonal antibody therapeutics are now serving important expanded roles in both early onset cases of COVID-19, as well as, for post vaccination breakthrough cases It is not however, a substitute for vaccination against COVID-19 Infections".

Vaccines

During the current COVID-19 pandemic the Messenger RNA vaccines and Viral vector based vaccines have been shown to be highly effective in the realm of prevention from infection with COVID-19 infections [1,2]. The vaccines preparations have additional beneficial consequences as relates to the lessening of the pathogenic consequences (ie hospitalizations, Long Hauler scenarios and death) of this viral infection(1-8). More recently these vaccines have also been shown to be protective against the new Delta Variant strains of COVID-19 [2].

Monoclonal antibodies in early onset covid-19 infections

At the present time Vaccines, offer the best protection against COVID-19 infections [1,2]. The United States Food and drug administration under the Emergency Utilization Guidelines has authorized the use of monoclonal antibody based therapeutics for early onset infections. The application of Monoclonal antibodies has been applied to patients that have manifested symptoms for a period of up to 10 days, and who have been categorized as high risk patients for displaying serious disease pathology [9,10].

Monoclonal antibody therapeutics have been found to bring about a lessening of the severity of the COVID-19 infection and also a lowering of the patient's risk of dying from COVID-10 [9,10]. The patients that have been selected for monoclonal antibody therapeutics were high risk adults and high risk young people (12 - 17 years old). The young people had to have a minimum weight of 88 pounds to be eligible for treatment with monoclonal antibody therapy [9].

Monoclonal Antibodies have been synthesized in the lab and are specifically directed against COVID-19 [9]. Monoclonal antibody therapeutics are usually administered to the patient as an IV infusion or as an injection [9]. It has been noted that the reason why monoclonal antibody therapeutics have been so efficacious is that they have been found to lessen viral load [9]. A lowering of the viral load fosters milder symptoms and thus reduces the need for the patient to be hospitalized.

The Federal Drug Administration has given an authorization for the REGEN-COV product which consists of the combination of monoclonal antibodies (i.e. Casirivimab + Imdevimab) [9,10]. This monoclonal therapeutic has even been utilized in patients that had been exposed the COVID-19 viral pathogen but had not manifested symptoms of the viral infection [9]. In addition, monoclonal therapeutics

have been given to individuals who had not had full vaccination, as well as those individuals that were classified as being immunocompromised (i.e. this condition also included patients on immunosuppressive regimens) [9]. A further qualification for receiving monoclonal antibody therapeutics as a prevention therapy was that the individual was engaged in work or lived in an area that put them at high risk for COVID-19 infections [9].

Monoclonal antibody therapeutics to post vaccination breakthrough cases

Recently, a report in the literature cited a case of a 63 year old man with a breakthrough case of COVID-19 [11]. The man had been previously received two doses of Pfizer Vaccine [11]. This patient received monoclonal antibody therapy (i.e. bamlanivimab/etesevimab) and symptoms were resolved in 24 hours [11]. This case was one of the earliest cases reported in a hospital in New York City [11]. The successful application of Monoclonal Antibody among seniors who have had post vaccination breakthrough was recently reported by a physician treating COVID-19 patients at a local rural hospital in New Jersey [12].

The FDA has now revised their recommendations for the additional use of Monoclonal Antibody therapeutics to cover the post exposure prophylaxis [13]. These new regulations are for the utilization of REGEN COV (casirivimab and imdevimab given together) [13]. The FDA applications are for adults and pediatric patients (patients 12 years or older weighting at least 40 kg) [13]. The FDA now recommends monoclonal antibody therapy is to be utilized for patients that are at high risk for the progression of COV-19 infection to severe illness with hospitalization and a possible outcome risk of death [12]. The original application of monoclonal antibody therapeutics using REGEN-COV can still be used to treat mild to moderate cases of COVID-19 in adults or children aged 12 or older with a body weight of at least 40 kg.

A point that the FDA makes quite clear is that **"**Prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19".

Monoclonal antibody therapeutics are now serving important expanded roles in both early onset cases of COVID-19, as well as, for post vaccination breakthrough cases It is not however, a substitute for vaccination against COVID-19 Infections.

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