

Does Remdesivir maintain the race in the general treatment protocol of COVID-19?

Dear Editor,

With great interest, we recently read the review by Bajpai *et al.*^[1] supporting Remdesivir—Current evidence and perspective in the management of COVID-19 infection published on June 23, 2021. However, we think that the review should be interpreted cautiously because of the changes made by the Ministry of Health and Family Welfare (MOHFW), which was to stop the irrational use and over prescription of Remdesivir, a reserve/experimental/emergency-use authorized drug.^[2] From the beginning of this COVID-19 pandemic, we are one of the tertiary care centers with maximum usage as well as utilization of Remdesivir in Central India. So, at this current juncture, we try to add some additional important points by our experience in using Remdesivir and these maybe considered as updated review points for the same.

By the sudden emergence of COVID-19, there are various treatment modalities and no treatment is specific and proven to be effective against COVID-19 till date. Remdesivir is the only officially approved drug by Food and Drug Administration (FDA) on October 22, 2020 under the category of Emergency Use Authorization (EUA) for hospitalized patients with COVID-19.^[3]

Frediansyah A said that Remdesivir has been used in several countries as an emergency drug but, only some patients in hospital settings showed clinical improvement. He also suggested for large-scale clinical trials to confirm the efficacy of Remdesivir in treating patients with COVID-19.^[4] A study conducted by Wang and colleagues showed that there was no difference in the decline in viral titers between Remdesivir and placebo.^[5] Garcia-Vidal C *et al.* said that the usage of Remdesivir in severe COVID-19 patients who require high-flow oxygen or mechanical ventilation was uncertain. However, information about viral shedding in humans receiving Remdesivir treatment is lacking, which is important to define the duration of transmissibility and the potential consequences on the isolation measures.^[3]

As per the recent guidelines by Government of India, Ministry of Health and Family Welfare (MOHFW) dated on April 23, 2021, Remdesivir should be used under EUA as an off-label drug only in selective, moderate and severe, hospitalized COVID-19 patients who are on supplemental oxygen admitted within 10 days of

the onset of disease.^[2] EUA is different from an approved drug, which can be used in urgent, serious, and life-threatening conditions. Also clinicians are advised to use it with caution as it is only an experimental drug with potential to harm and has relatively high cost with limited availability.^[2] On May 24, 2021, some additional conditions were added for the nonusage of Remdesivir in patients with a) renal or hepatic dysfunction (eGFR 5 times ULN [Upper Limit of Normal] but not an absolute contradiction) b) Pregnancy or lactating female patients c) Children <12 years of age, and d) patients who are not on oxygen support or in home settings.^[6] On June 2021 guidelines, Remdesivir was not recommended for use in children below 18 years of age due to lack of sufficient evidence on safety and efficacy in them.^[7]

In the second wave of COVID-19, the shortage of Remdesivir had been reported across the country and social media was flooded with posts of family members and friends of COVID-19 patients requesting for Remdesivir, and some reports suggested that it had been sold in the black market at very high prices.^[8] Even though the mechanism of this drug appears to be promising, the actual effect on patients is not more evident. In India, MOHFW also recommended it as an investigational therapy in their COVID-19 management protocol; however, it clarified that it is not a “life-saving drug.” It is a misconception that Remdesivir is a miracle cure for COVID-19. In fact, most of the patients don't require Remdesivir for surviving this disease.^[9]

In some states of South India,^[10] Remdesivir was hyped to be a life-saving drug. Even admission and management had been planned based on availability of Remdesivir, despite guidelines issued by MOHFW regarding its off-label status. So, as an off-label and emergency-use authorized drug, it should be prescribed based upon the indication criteria of MOHFW, which may be proclaimed on a case-to-case basis with government conditions like in India.

So at this current stage, the standard operative procedure (SOP) has to be drafted for every tertiary care unit for the optimal use of Remdesivir only for indicated patients. It is being noteworthy to mention here that the same strategy of SOP was being implemented for rationale and the optimal usage of Remdesivir with strict monitoring for the indication, and the same is being depicted in the figure. There is a huge control of its usage and it has been streamlined [Figure 1].

We appreciate the insights by Bajpai *et al.*^[1] and resonate deeply with many who are working tirelessly to prevent people from COVID-19 in their countries. This is a suggestion that Remdesivir is not a life-saving drug and various drug development processes should be integrated urgently as part of the response to this pandemic.

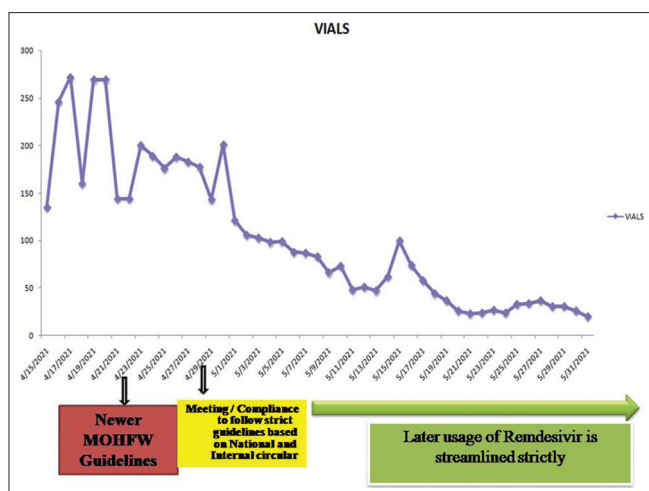


Figure 1: Usage of Remdesivir Pre and Post SOP and monitoring

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Conflicts of interest

There are no conflicts of interest.

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