Remdesivir use in a community hospital

Amelia Gooch, PharmD; Kathryn Lincoln, PharmD, BCPS, BCIDP
Olathe Health

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Background

- Remdesivir (RDV) is an FDA-approved antiviral therapy for patients infected with the SARS-CoV-2 virus, also known as COVID-19.
- RDV works by inhibiting RNA replication; therefore, it is most effective when the COVID-19 virus is actively replicating.
- In order to ensure RDV's safe and effective use, the Pharmacy, Therapeutics, and Dietary subcommittee: COVID-19 Therapeutics developed criteria for RDV use.
- RDV costs between $3000-$6000 per treatment course.
- At the time this medication-use evaluation (MUE) was conducted, RDV was restricted to an infectious diseases or pulmonary provider.
- The purpose of this MUE was to assess the adherence to our institution's criteria for use.

Criteria For Use

Inclusion Criteria

- Hospitalized patients with laboratory confirmed COVID-19
- Within 12 days of symptom onset
- Oxygen saturation ≤ 94% on room air, require supplemental oxygenation or mechanical ventilation

Exclusion Criteria

- Liver function tests (LFTs) greater than 5 times the upper limit of normal (ULN)
- Estimated glomerular filtration rate (eGFR) less than 30 mL/min

Methods

- The study period was between May 1, 2020 to October 1, 2020.
- Baseline demographics collected include age, sex, race, body mass index (BMI), and comorbid conditions.
- Adherence to the institutional criteria for use was evaluated for patients receiving RDV.
- LFTs were monitored at the beginning and end of RDV treatment.
- The use of other COVID-19 treatments were assessed, including use of azithromycin, dexamethasone, and convalescent plasma.

References:
- Veklury (remdesivir) [package insert]. Giliead Sciences, Inc., October 2020.
- COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health.

Contact: Amelia Gooch, PharmD at Amelia.Gooch@olathehealth.org

Disclosures:
Nothing to disclose

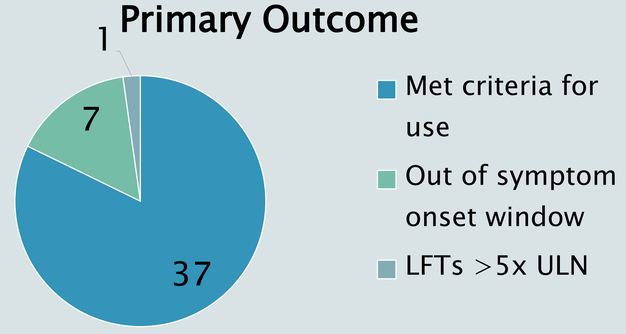
Results

Baseline Demographics* (N=45)	
Age (years)	59.1 (±13.0)
Male	25 (55.5%)
BMI (kg/m²)	35.1 (±9.7)
Ethnicity	
• White	35 (77.8%)
• Hispanic	6 (13.3%)
• African American	2 (4.4%)
• Asian	2 (4.4%)
Co-morbid conditions	
• Hypertension	25 (55.6%)
• Type 2 diabetes mellitus	17 (37.8%)
• Heart condition#	10 (22.2%)
• Obstructive sleep apnea	6 (13.3%)
• Reactive airway disease	3 (6.7%)
LFTs at baseline+	
• Within normal limits (WNL)	14 (31.1%)
• Elevated, but <5x ULN	27 (60.0%)
• >5x UNL	1 (2.2%)
Mechanical ventilation	
• At start of RDV therapy	3 (6.5%)
• During hospitalization	12 (26.7%)

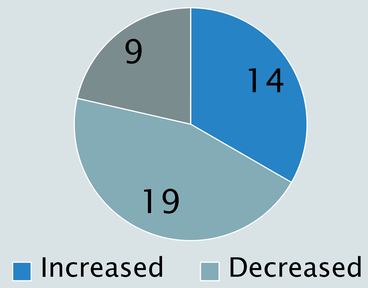
*All patients required at least supplemental oxygen and met eGFR requirement
#Heart disease, atrial fibrillation, heart failure
+ULN defined as ALT= 49 unit/L, AST= 33 unit/L, alkaline phosphatase=116 unit/L

Other Therapies Received (N=45)	
Convalescent plasma	36 (80.0%)
Dexamethasone	35 (77.8%)
Azithromycin	35 (77.8%)
Other antibiotics	40 (88.9%)

Primary Outcome

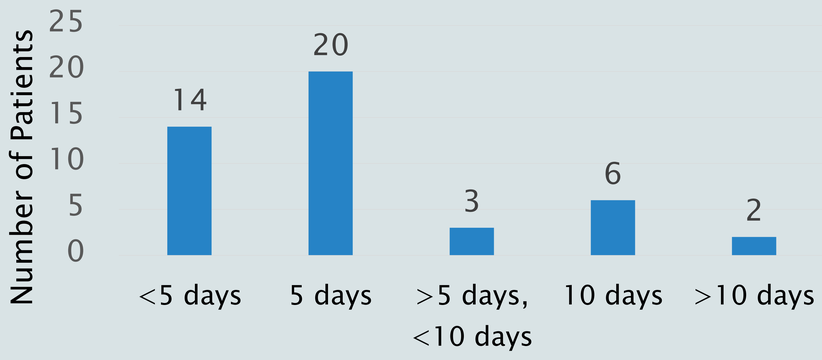


LFT Trends at End of Treatment



LFTs increased to >5x ULN in two patients
- One patient stopped RDV
- One patient did not have LFTs ordered daily, so elevation was found after 10th dose

RDV Days of Therapy



Discussion

- Thirty-seven (82.2%) patients who received RDV met our institution's criteria for use.
- RDV has not impacted liver function clinically.
- Since this MUE was conducted, we now have an order set for RDV that includes the updated criteria for use and daily hepatic function panel.
- Now with established criteria, providers understand that not every patient is a candidate for RDV therapy.
- Pharmacists review RDV criteria during order verification.

Conclusion

- Criteria for use has been updated since this MUE was completed: LFT cutoff has been increased to 10 times the upper limit of normal, there is no longer an eGFR cutoff, symptom onset is 7 days, and patients on mechanical ventilation are excluded.
- Duration of therapy is limited to 5 days
- More is known about COVID-19 and RDV now, so many of these patients would not have met criteria for use due to time from symptom onset.