Clinical Characteristics of Patients With Severe COVID-19 From Washington State, FDA Allows Expanded Use of Devices to Monitor Patients' Vital Signs Remotely

NEW YORK -- March 20, 2020 -- Today's DG Alert covers clinical characteristics of patients with severe coronavirus disease 2019 (COVID-19) from Washington State, and a new policy from the US Food and Drug Administration (FDA) that allows certain vital sign-measuring devices to be used remotely.

A study published in JAMA describes the clinical presentation, characteristics, and outcomes of patients with severe COVID-19 who were treated at Evergreen Hospital, Kirkland, Washington.

Between February 20, 2020, and March 5, 2020, 21 patients (52% male) aged 43 to 92 years with COVID-19 at Evergreen Hospital -- a public hospital with 20 intensive care unit (ICU) beds serving approximately 850,000 residents in Washington State. Of the patients, 86% had comorbidities, the most common being chronic kidney disease (47.6%), congestive heart failure (42.9%), chronic obstructive pulmonary disease (33.3%), and diabetes (33.3%).

When patients presented to the hospital, the most common initial symptoms included shortness of breath (76%), fever (52%), and cough (48%). The mean onset of symptoms prior to presenting to the hospital was 3.5 days, and 17 patients (81%) were admitted to the ICU less than 24 hours after hospital admission. Two patients were co-infected with other respiratory illnesses (influenza A and parainfluenza type 3).

An abnormal chest radiograph was observed in 20 (95%) patients at admission. The most common findings on initial radiograph were bilateral reticulonodular opacities (52%) and ground-glass opacities (48%). The mean white blood cell count was 9,365 µL at admission and 14 patients (67%) had a white blood cell count in the normal range. Fourteen (67%) patients had an absolute lymphocyte count of <1000 cells/µL.

Mechanical ventilation was initiated in 15 (71%) patients. Acute respiratory distress syndrome (ARDS) was observed in all patients requiring mechanical ventilation. By 72 hours, 8 of the 15 (53%) patients developed severe ARDS. Cardiomyopathy developed in 7 (33%) patients.

As of March 17, 2020, 11 patients died, 2 survived to transfer out of the ICU, and 8 remain critically ill and require mechanical ventilation.

"This study represents the first description of critically ill patients infected with SARS-CoV-2 in the United States," concluded Matthew Arentz, MD, University of Washington, Seattle, Washington, and Eric Yim, MD, Evergreen Hospital, and colleagues. "These patients had a high rate of ARDS and a high risk of death, similar to published data from China. However, this case series adds insight into the presentation and early outcomes in this population and demonstrates poor short-term outcomes among patients requiring mechanical ventilation."

As part of the ongoing efforts to address the COVID-19 pandemic, the FDA has issued a new policy that allows manufacturers of certain FDA-cleared non-invasive, vital sign-measuring devices to expand their use so that healthcare providers can use them to monitor patients remotely.

The devices include those that measure body temperature, respiratory rate, heart rate, and blood pressure.

Allowing these devices to be used remotely can help healthcare providers access information about a patient's vital signs while the patient is at home, reducing the need for hospital visits and minimising the risk of exposure to coronavirus," said Amy Abernethy, MD, FDA, Rockville, Maryland.

The policy will remain in place for the duration of this emergency.

Reference: https://jamanetwork.com/journals/jama/fullarticle/2763485