Using Ventilator Splitters During the COVID-19 Pandemic - Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) is informing health care providers and health care facilities about up-to-date information concerning multiplexing ventilator tubing connectors, also known as ventilator splitters, in situations in which no alternatives for invasive ventilatory support are available.

Although the FDA has not received any adverse event reports related to the use of ventilator splitters authorized for emergency use during the COVID-19 pandemic, recent literature[i],[ii],[iii] describes risks that may be associated with using certain ventilator splitters. After considering this recent literature, the FDA is informing health care providers and health care facilities that the literature indicates that certain features are associated with better performance.

Considerations for Health Care Providers

Health care providers and facilities should review the considerations listed below:

- Consider non-invasive ventilation such as high flow nasal oxygen or non-invasive positive pressure ventilation as a first option prior to using an authorized ventilator splitter.
- If invasive ventilation using an authorized ventilator splitter is the only option:
    - Limit sharing of ventilation to two patients,
    - Try to match patients based on similar ventilatory requirements,
    - Limit duration of sharing ventilation to 48 hours,
    - If possible, reserve at least one single patient ventilator for emergencies or to wean a patient off ventilation support
    - Consider updated ventilator sharing protocols, such as the New York Presbyterian Ventilator Sharing Protocol: Dual-Patient Ventilation with a Single Mechanical Ventilator for Use during Critical Ventilator Shortages (https://protocols.nyp.org/Documents/Ventilator_Sharing_Protocol.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to minimize risk.
- The recent literature indicates that ventilator splitters that incorporate these features may reduce certain risks:
    - One-way valves in the breathing circuit,
    - Flow restrictors or pressure regulators at each inspiratory limb of the circuit,

- Individual positive end-expiratory pressure (PEEP) valves,
- Inspiratory and expiratory tidal volume sensors, and
- Pressure sensors.

Background

Ventilator splitters divide the gas flow from a single mechanical ventilator to deliver a tidal volume to more than one patient and collect expiration from these patients.

On March 25, 2020, the FDA issued an Emergency Use Authorization (/media/136423/download) (EUA) that authorizes the emergency use of certain ventilators and ventilator accessories for treating patients during the COVID-19 pandemic to address the observed and anticipated shortages of ventilators and ventilator accessories. The FDA updates the list of authorized devices regularly, see Appendix B: Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas#appendixb).

The FDA issued this EUA for ventilator splitters based in part on data from two preclinical studies that showed that ventilator splitters may be effective in providing ventilation to multiple patients from a single ventilator. In consideration of an imminent projected shortage of ventilators at that time, and based on the available information at the time, the FDA concluded that the known and potential benefits of using ventilator splitters outweighed the known and potential risks.[iv]

During the past nine months of the pandemic, clinicians have gained real-world experience with shared ventilators and additional research has been performed on the conditions for safe use. These activities greatly increased the understanding of the known and potential risks and benefits of ventilator splitters in a very short time.[v],[vi]

Some of the challenges identified in reported clinical experience include:

- The need to continually balance differences in respiratory mechanics of both co-vented patients;
- The need for paralysis and deep sedation to prevent asynchrony;
- Swinging air from one co-vented patient to another (pendelluft), resulting in lung injury due to overdistension of the alveoli (volutrauma), or inspired carbon dioxide;
- The increased complexity of clinical decision making; and
- The lack of individual ventilator alarms to alert individual ventilation problems.

These findings highlight the importance of only using ventilator splitters in situations where there are no other alternatives for invasive ventilation, and in accordance with the recommendations outlined above.

These reported challenges, and an evidence-based lung model simulating a range of patients' pulmonary resistances and compliances (which are measures of the stiffness and elasticity of the lungs), suggest that specific design features may result in more effective pulmonary support . Specifically, incorporation of one-way valves in the breathing circuit can reduce the pendelluft phenomenon, thereby reducing the likelihood of volutrauma and the exchange of gases between patients. The addition of flow restrictors and pressure regulators at each inspiratory limb of the circuit, individual PEEP valves, inspiratory and expiratory tidal volume and pressure sensors can assist in monitoring and adjusting the gas delivery to meet the needs of individual patients.

FDA Actions

The FDA is monitoring clinical experience with ventilator splitters during the COVID-19 pandemic and is continuing to evaluate the emergency use authorization of these devices.

The FDA plans to keep health care providers and the public informed if significant new information becomes available.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with ventilator splitters.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) (DICE).

[i] Hess DR, et al. Ventilator sharing: the good, the bad, and the ugly. Respir Care 2020; 65(7): 1059-1061.

[ii] Beitler, JR et al. Ventilator sharing during an acute shortage caused by the COVID-19 pandemic. AJRCCM 2020;202(4):600-604.

[iii] Neyman G, Irvin CB. A single ventilator for multiple simulated patients to meet disaster surge. Acad Emerg Med 2006;13(11):1246-1249.

[iv] Paladino L, et al. Increasing ventilator surge capacity in disasters: ventilation of four adult-human-sized sheep on a single ventilator with a modified circuit. Resuscitation 2008;77(1):121-126.

[v] Chatburn RL et al. Multiplex ventilation: a simulation-based study of ventilating 2 patients with a single ventilator. Respir Care 2020;65(7):920-931.

[vi] Laffey JG et al. Supporting more than one patient with a single mechanical ventilator: useful last resort or unjustifiable risk? Brit J Anaesth 2020;125(3):247-250.