

# Clinical Evaluation Summary Report

**Date of Summary:** 7/25/18

Case study      Quality Improvement Project      Clinical investigation      Results of Database search

**Investigation/case conducted by:** Yasuhiro Shudo, MD, PhD, Patpilai Kasinpila, MD, Anson M. Lee, MD, Vidya K. Rao, MD, MBA, and Y. Joseph Woo, MD, Stanford, California.

**Location(s) of Investigation:** Department of Cardiothoracic Surgery, Stanford University School of Medicine, Stanford, Calif; and department of Anesthesiology, Perioperative and Pain Medicine, Stanford University School of Medicine, Stanford, Calif.

**Number of patients involved:** 1

**Duration of the study:** Case report over 32 days. 20 days of ECMO up until Heart and Lung organs became available, then on post-operative day 12, she was discharged without complication.

**Timeline of study:** 2017

**Description of patient groups (demographics and/or condition studied):** A 41-year-old woman, who was listed for Heart and Lung transplant because of Idiopathic Pulmonary Hypertension and inotrope-dependent right heart failure, developed hemoptysis and progressive hypoxic respiratory failure that were refractory to escalating ventilatory support. She underwent percutaneous cannulation for veno-arterial extracorporeal membrane oxygenation (VA-ECMO) via the right femoral vein and left common femoral artery.

**Description of the study (attach additional pages if necessary)** The case study described how the multidisciplinary team aimed to ambulate the patient towards optimizing her physical condition in readiness for her heart and lung transplant. The patient was placed on a Vitalgo Tilting bed to begin working on her endurance. She had daily physical therapy on the bed. Initially, she could tolerate 45-degree tilt and 40% weight-bearing for 30 minutes. By ECMO day 9, she could tolerate full tilt and weight-bearing for 30 minutes. The team then progressed her to walking off the bed in full vertical tilt. The study describes the method of securing the cannulas, and tubing, and describes the roles of each discipline during the ambulation from the bed. By ECMO day 15, the patient could ambulate for 30 minutes with minimal assistance.

**Summary of study results:** This patient received a heart and lung transplant on day 20 of ECMO, and was discharged on day 12 after transplant, with no post-operative complications. She was able to resume all physical activities without limitations or symptoms. The authors concluded that the progressive multidisciplinary ambulation approach, which included standing, ambulating and exercises while waiting for her transplant, helped reduce the risks of developing atelectasis and pneumonia, and possibly reduced her risk of postoperative complications. The authors also noted no movement of the femoral catheters during ambulation. The overall conclusion was that mobilizing and ambulating patients with femoral cannulation are feasible and safe, and may actually offer benefits with regard to postoperative outcomes.

## **Critical evaluation of the results:**

This is an important clinical application of the Vitalgo Total Lift Bed. It is limited to one patient experience, however, the safety and feasibility of mobilizing patients with femoral cannulas undergoing Extra-Corporeal Membranous Oxygenation (ECMO) is very important. The implications are that by standing and walking patients before transplant safely, risks and complications of this procedure may be able to be minimized. Larger studies are needed, but this is a very important first step.

**Relevance of results for Risk analysis or design processes:** Standing and ambulating patients from the total lift bed is safe and feasible for patients undergoing femoral cannula ECMO. This study is currently In Press.



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Shudo Y, Kasinpila P, Lee AM, Rao VK, and Woo YJ. Ambulating femoral venoarterial extracorporeal membrane oxygenation bridge to heart-lung transplant. *The Journal of Thoracic and Cardiovascular Surgery*. c Volume - , Number

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