



Lung Assist Device Provides Bridge to Transplant

The device has been used on about 500 patients in Europe with pneumonia and other lung disorders.

BY MITCHEL L. ZOLER
Editor Global Medical News

PHILADELPHIA — A new lung assist device improves physiologic measures in patients who are awaiting a lung transplant and allows them to avoid mechanical ventilation and extracorporeal membrane oxygenation.

"This is the first effective bridge to lung transplant for patients with ventilator-refractory lung failure," Stefan Fischer, M.D., said at the annual meeting of the International Society for Heart and Lung Transplantation. He reported on his group's experience with the device, named *Novalung*, on 12 of 176 patients who underwent lung transplants at Hannover (Germany) Medical School from March 2003 through March 2005.

Before treatment with the device, all 12 patients were hypoxemic and hypercapnic and had respiratory acidosis.

Patients remained prone while attached to the *Novalung*, which was placed between their legs.

One canula routed blood from a femoral artery into the device, where the blood was oxygenated, and then returned through a second canula into a femoral vein in the other leg. The device does not use a mechanical pump; it relies on the pa-

tient's ventricular pressure to drive the blood.

Six hours on the device yielded significant improvements in hypercapnia and acidosis, but little efficacy in reversing hypoxemia, said Dr. Fischer, a cardiothoracic surgeon in Hannover.

Prior to treatment, the average PaCO₂ was about 130 mm Hg, which fell after 6 hours on the device to an average of less than 60 mm Hg. Before treatment, serum pH averaged 7.12, which rose after 6 hours to a mean of 7.35. But PaO₂ levels were less responsive to treatment, rising from an average of about 70 mm Hg before treatment to an average of about 80 mm Hg after 6 hours on *Novalung*, he reported.

The average flow rate through the lung assist device in these patients was 1.8-2.4 L/min. "This is enough to get rid of the [excess] carbon dioxide, but there is a problem with oxygen. If a patient has a severe oxygen deficiency, it won't work no matter what you do," he said.

Patients were kept on the device for an average of 15 days (range of 4-32 days) before it was removed following lung transplant. In this series, 10 of the 12 treated patients went on to a successful lung transplant.

Seven patients had an absolute contraindication for treatment by extracor-



COURTESY DR. STEFAN FISCHER

The *Novalung*, which is placed between the legs entering the groin (top), relies on ventricular pressure to drive the blood.

poral membrane oxygenation (ECMO), such as a severe systemic infection. Eight patients have remained alive during an average follow-up of 305 days from the time they began *Novalung* treatment, Dr. Fischer said. Use of the device precluded the need for mechanical ventilation, which raises the risk for poor outcomes following lung transplant. Treatment with ECMO before a lung transplant is also linked with poor outcomes following transplantation. In the Hannover transplant program, patients treated with ECMO before the procedure had a 40% survival rate during the following year, Dr. Fischer said.

"Patients have a better chance [of surviving] with the *Novalung* than with ECMO," he said.

This series received no financial support from *Novalung*, the German company that makes the device.

The device has been used on about 500 patients in Europe with a range of disorders, including severe pneumonia, acute respiratory distress

syndrome, and chemical lung injury. It sells in Germany for about 4,000-5,000 euro, plus the cost of disposable supplies, but it is not yet approved for use in the United States. The design was licensed to *Novalung* by MC3, a device company in Ann Arbor, Mich., that is developing a U.S. version named *Biolung*, currently in animal testing.

Contraindications for *Novalung* include cardiogenic shock, a mean arterial blood pressure of less than 60 mm Hg, and severe atherosclerosis in the femoral artery. All three conditions would interfere with adequate blood flow through the device and back to the patient. ■