

Helmet-Based Ventilation Had Better Results than Facemask for ARDS Patients



Results of a trial of helmet-based ventilation have shown that using a transparent air-tight helmet instead of a facemask helped critically ill patients breathe better and reduced their need for mechanical ventilation. In the trial, patients who were treated with helmet ventilation spent less time in the intensive care unit and lower mortality. The trial was stopped early as it was felt enrolling more patients in the control group would not be justified. The study is published early online in [JAMA](#).

In the [Non-Invasive Ventilation Via a Helmet Device for Patients Respiratory Failure clinical trial \(NCT01680783\)](#), 83 patients suffering from acute respiratory distress syndrome (ARDS) were randomly assigned to receive either a standard facemask [Philips Respirionics] (39 patients), or the latex-free helmet [Sea Long] (44 patients), which surrounds the patient's entire head and is sealed with a soft air-tight collar that wraps around the patient's neck (see image above). The trial had originally planned to enrol 103 patients per group. The patients enrolled were severely ill with a 50 percent risk of requiring intubation or dying in the intensive care unit (ICU). About half of the patients had weakened immune systems from cancer or transplantation. Eligible patients had received facemask noninvasive ventilation (NIV) for at least 8 hours as part of their usual clinical care. Participants were assigned to continue NIV via oronasal face mask or switch to NIV delivered via a plastic, transparent helmet.

"In this group of critically ill patients, the helmet made a substantial difference," said pulmonologist [John P. Kress, MD, professor of medicine at the University of Chicago](#) and senior author of the study. "The University's data and safety monitoring board recommended that we stop the trial early because the helmet consistently demonstrated multiple advantages, particularly the reduced need to intubate patients and longer-term reduction in mortality."

See Also: [Noninvasive Ventilation](#)

The researchers found several advantages for the helmet compared to the facemask. The helmet is less likely to leak, more comfortable, easier for the patient to tolerate because it is away from the face, and its transparency means patients can see well enough to watch TV, talk or read. The helmet's design allows the care team to increase air pressure into the helmet.

Patients in the helmet group were three times less likely to require intubation. Only 18.2 percent of those wearing a helmet required an endotracheal tube, versus 61.5 percent of those wearing a facemask. The helmet group had, on average, more ventilator-free days (28 vs 12.5). Helmet patients also had lower mortality. When compared at 90 days, 34 percent (15 patients) in the helmet group had died, compared to 56 percent (22 patients) in the face mask group. Adverse trial-related events were minor, and included 3 skin ulcers for each group.

"These findings build on a shifting paradigm where less is more in the care of critically ill patients," said first author [Bhakti Patel, MD, clinical instructor of medicine](#) at the University. "We have chosen less sedation for more mental animation; less bed rest for more physical activity; and now we're choosing less intubations for more noninvasive ventilation."

In an accompanying editorial, Jeremy R. Beitler, MD, MPH, University of California, San Diego, with Robert L. Owens, MD and Atul Malhotra, MD recommend that future studies report interruptions to wearing the prescribed NIV interface continuously, leak severity, biomarkers of lung injury, and sedative administration to help delineate potential mechanisms. They write: "Without standardizing NIV initiation, it is difficult to ascertain for whom precisely helmet NIV should be considered." They acknowledge the key messages of the study. The helmet has unique advantages and disadvantages that may influence efficacy of NIV, depending on patient and disease characteristics. They suggest that before clinicians consider using helmet NIV routinely in select ARDS patients multicentre studies are needed and clarification of the appropriate eligibility criteria, optimal ventilator settings and potential mechanisms of effect. They conclude: "it is increasingly clear that there may be an important albeit underinvestigated role for some form of high-level noninvasive respiratory support to prevent intubation, and perhaps mortality, in acute hypoxemic respiratory failure."

LIPS-A: Lung Injury Prevention Study With Aspirin Reports Results

Also published online in JAMA on 15 May are the results of the phase2b trial [LIPS-A: Lung Injury Prevention Study With Aspirin](#). Daryl J. Kor, MD, MSc, Department of Anesthesiology, Mayo Clinic College of Medicine, Rochester, Minnesota and colleagues report that among at-risk patients presenting to the ED, the use of aspirin compared with placebo did not reduce the risk of ARDS at 7 days. They write that the findings of this

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phase 2b trial do not support continuation to a larger phase 3 trial.

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