



Study: Sedation Protocol Does Not Reduce Time of Respiratory Support



The use of a nurse-implemented, goal-directed sedation protocol compared with usual care did not reduce the duration of mechanical ventilation in children with acute respiratory failure, according to a University of Pennsylvania-led study published in *JAMA*.

Sedation therapy benefits critically ill infants and children; however, it is also associated with adverse effects. While numerous studies in adult critical care support a minimal yet effective approach to sedation management, only few data inform sedation practices in paediatric critical care, the researchers noted.

The study (RESTORE) was conducted from 2009-2013. Researchers evaluated 2,449 children (average age, 4.7 years) mechanically ventilated for acute respiratory failure in paediatric intensive care units (PICUs) to a sedation intervention (17 sites; n = 1,225 patients) or sedation with usual care (14 sites; n = 1,224 patients). The intervention PICUs used a protocol that included targeted sedation, arousal assessments, extubation (removal of breathing tube) readiness testing, sedation adjustment every 8 hours and sedation weaning. Patients were followed up until 72 hours after opioids were discontinued, 28 days, or hospital discharge.

The duration of mechanical ventilation, the primary outcome for the study, was not different between the two groups (intervention: median, 6.5 days vs. control: median, 6.5 days). The research team, led by Martha A.Q. Curley, RN, PhD, of the University of Pennsylvania in Philadelphia, reported these other key findings:

- No group differences in the time to recovery from acute respiratory failure, duration of weaning from mechanical ventilation, PICU and hospital lengths of stay or 28- or 90-day in-hospital mortality;
- No significant differences in sedation-related adverse events including inadequate pain management, inadequate sedation management, extubation failure, ventilator-associated pneumonia, catheter-associated bloodstream infection, or new tracheostomy; and
- Intervention patients experienced more postextubation stridor (an abnormal sound made when the breathing passages are narrowed; 7 percent vs. 4 percent) and fewer stage 2 or worse immobility-related pressure ulcers (<1 percent vs. 2 percent).

The results of the study were presented at the Society of Critical Care Medicine's 44th Critical Care Congress.

"Exploratory analyses of several secondary outcomes indicated that the sedation protocol was associated with a difference in patients' sedation experience," the research team said. "Patients in the intervention group were able to be safely managed in a more awake and calm state while intubated, receiving fewer days of opioid exposure and fewer sedative classes without an increase in inadequate pain or sedation management or

clinically significant iatrogenic withdrawal compared with patients receiving usual care, but they experienced more days with reported pain and agitation, suggesting a complex relationship among wakefulness, pain, and agitation.”

While this focused on the process of how sedatives are administered, future studies should compare the best sedative agent for varied lengths of critical illness, the researchers added. “Outcomes of interest include efficacy as well as an evaluation of the immediate risk-benefit ratio and an evaluation of the long-term effect of sedatives on neurocognitive development and posttraumatic stress.”

In an accompanying [editorial](#), Sangeeta Mehta, MD, FRCPC, of Mount Sinai Hospital and the University of Toronto, writes: “Curley and colleagues answered the call for the conduct of a large clinical trial in children and have contributed valuable data to help advance approaches to sedation management in critically ill children.

“While it is disappointing that this trial showed no advantage of a complex sedation management strategy, it is reassuring that the overall clinical outcomes related to ‘usual care’ in the 14 control PICUs were not significantly different than protocolised sedation in the intervention PICUs. It is imperative that high-quality research in this field continues, not only to learn more about the short- and long-term effects of sedation strategies but, more importantly, to improve clinical care and outcomes for these vulnerable patients.”

Source: [JAMA](#)

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