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A protocol of no sedation for critically ill patients receiving mechanical ventilation: a randomised trial.

Strøm T¹, Martinussen T, Toft P.

Author information

Abstract

BACKGROUND: Standard treatment of critically ill patients undergoing mechanical ventilation is continuous sedation. Daily interruption of sedation has a beneficial effect, and in the general intensive care unit of Odense University Hospital, Denmark, standard practice is a protocol of no sedation. We aimed to establish whether duration of mechanical ventilation could be reduced with a protocol of no sedation versus daily interruption of sedation.

METHODS: Of 428 patients assessed for eligibility, we enrolled 140 critically ill adult patients who were undergoing mechanical ventilation and were expected to need ventilation for more than 24 h. Patients were randomly assigned in a 1:1 ratio (unblinded) to receive: no sedation (n=70 patients); or sedation (20 mg/mL propofol for 48 h, 1 mg/mL midazolam thereafter) with daily interruption until awake (n=70, control group). Both groups were treated with bolus doses of morphine (2.5 or 5 mg). The primary outcome was the number of days without mechanical ventilation in a 28-day period, and we also recorded the length of stay in the intensive care unit (from admission to 28 days) and in hospital (from admission to 90 days). Analysis was by intention to treat. This study is registered with ClinicalTrials.gov, number [NCT00466492](#).

FINDINGS: 27 patients died or were successfully extubated within 48 h, and, as per our study design, were excluded from the study and statistical analysis. Patients receiving no sedation had significantly more days without ventilation (n=55; mean 13.8 days, SD 11.0) than did those receiving interrupted sedation (n=58; mean 9.6 days, SD 10.0; mean difference 4.2 days, 95% CI 0.3-8.1; p=0.0191). No sedation was also associated with a shorter stay in the intensive care unit (HR 1.86, 95% CI 1.05-3.23; p=0.0316), and, for the first 30 days studied, in hospital (3.57, 1.52-9.09; p=0.0039), than was interrupted sedation. No difference was recorded in the occurrences of accidental extubations, the need for CT or MRI brain scans, or ventilator-associated pneumonia. Agitated delirium was more frequent in the intervention group than in the control group (n=11, 20% vs n=4, 7%; p=0.0400).

INTERPRETATION: No sedation of critically ill patients receiving mechanical ventilation is associated with an increase in days without ventilation. A multicentre study is needed to establish whether this effect can be reproduced in other facilities.

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