TITLE: The Effect of Supplementation of Vitamin D in Neurocritical Care Patients with Hypovitaminosis D: A Randomized Controlled Clinical Trial.

SPEAKER: Michael Karsy, M.D. CITY/STATE: Salt Lake City, UT

AUTHORS: Michael Karsy, MD, PhD, MSc; Jian Guan, MD; Ilyas El, MD; Andrea A. Brock, MD, MSCI; Sarah T. Menacho, MD; Min S. Park, MD; Randomized Clinical Trial of Hypovitaminosis (RECTIFY)

ABSTRACT:

Objective: Hypovitaminosis D is prevalent in neurocritical care patients, but the potential to improve patient outcome by replenishing vitamin D has not been investigated. This single-center, double-blinded, placebo-controlled, randomized (1:1) clinical trial was designed to assess the effect on patient outcome of vitamin D supplementation in neurocritical care patients with hypovitaminosis D (NCT02881957).

Methods: From October 2016 until April 2018, emergently admitted neurocritical care patients with vitamin D deficiency (≤20 ng/ml) were randomized to receive vitamin D3 (cholecalciferol, 540,000 IU) (n=134) or placebo (n = 133). Hospital length of stay (LOS) was the primary outcome; secondary outcomes included intensive care unit (ICU) LOS, repeat vitamin D levels, patient complications, and patient disposition. Exploratory analysis evaluated specific subgroups of patients by LOS, Glasgow Coma Scale (GCS), and Simplified Acute Physiology Score (SAPS II).

Results: Two-hundred seventy-four patients were randomized (intent-to-treat) and 267 were administered treatment within 48 hours (as-treated; 61.2% of planned recruitment) and monitored. The mean age of as-treated patients was 54.0±17.2 years (56.9% male, 77.2% White). After interim analysis suggested a low conditional power for outcome difference (predictive power: 0.12), the trial was halted. For as-treated patients, no significant difference in hospital (10.4±14.5 vs. 9.1±7.9 days, p=0.4; mean difference=1.3, 95% CI= -1.5, 4.1) or ICU (ICU: 5.8±7.5 vs. 5.4±6.4 days, p=0.4; mean difference=0.4, 95% CI= -1.3, 2.1) LOS was seen between vitamin D3 and placebo groups. Vitamin D3 supplementation significantly improved repeat serum levels compared with placebo (20.8±9.3 vs. 12.8±4.8 ng/ml, p<.001) without adverse side effects. No subgroups were identified by exclusion of LOS outliers or segregation by GCS score, SAPS II score, or severe vitamin D deficiency (≤10 ng/ml).

Conclusions: Despite studies showing vitamin D can predict prognosis, supplementation in vitamin D–deficient neurocritical care patients did not result in appreciable improvement in outcomes and likely does not play a role in acute clinical recovery.