**[ 2:45 PM] A Pilot Randomized Controlled Trial of High-Dose Vitamin D in Lung Failure, [Publication Page: A5122]**

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Rationale: Immune dysfunction and nosocomial infections are important contributors to short-term and long-term survival after critical illness. Cost-effective adjunctive therapies that can be rapidly implemented to improve the host response are imperative. It is now well established that vitamin D has pleotrophic effects on immune cells by upregulation of antimicrobial peptides, (e.g. LL-37).
Methods: We completed a double blind, randomized, controlled trial to evaluate the safety and efficacy of two doses of vitamin D3 (total 250,000 IU or 500,000 IU over 5 days,) versus placebo in adult critically ill patients with respiratory failure. Our purpose was to determine whether high-dose vitamin D3 would increase plasma 25(OH)D and LL-37 levels (measured by chemiluminescence and ELISA, respectively) without adverse effects and whether this would improve clinical outcomes [hospital and ICU length of stay (LOS), ventilator days, SOFA score, hospital infection rate].

Results: 31 subjects were enrolled and completed the treatment protocol. Mean age was 62.9, 61% male, 47% Black, 42% surgical patients, 43% infection on admission, mean APACHE II score 22.4 and mean SOFA 7.6. These were equally balanced across all groups except for race. Aggregated mean values of 25 (OH)D and LL-37 were greater with Vitamin D3 treatment. (Table 1)

Table 1. 25(OH)D and LL-37 and Clinical Outcomes Across Groups.

| Variables | Placebo N=10 | 250K Vit D3 N=9 | 500K Vit D3 N=11 | P-Value |
|---|---|---|---|---|
| | Mean±SD | Mean±SD | Mean±SD | |
| Plasma 25(OH)D ng/mL through day 14 | 21.23±11.52 | 39.85±23.13 | 41.45±22.02 | *<.0001 |
| Plasma LL-37 ng/mL through day 14 | 77.00±53.38 | 109.26±125.29 | 147.25±131.51 | *0.04 |
| Hospital LOS | 23.11±18.55 | 23.11±14.10 | 18.45±10.76 | *0.03 |
| ICU LOS | 23.5±14.24 | 18.0±13.31 | 15.36±9.66 | 0.3 |
| Vent Days | 19.8±15.35 | 12.55±10.01 | 13.55±9.63 | 0.29 |
| Nosocomial infection | 3/10 (30) | 3/9 (33) | 2/11 (18) | 0.77 |
| SOFA score change | -1.8 | -5.4 | -3.5 | ±0.05 |

*P<0.05 compared across groups

± compared to group at baseline

Conclusion: This pilot randomized trial demonstrated that high dose vitamin D3 safely increased plasma 25(OH)D (p=<.0001) and significantly decreased hospital length of stay without altering infection rates or duration of ventilation. These data can inform the design of a larger, adequately powered randomized controlled trial on the efficacy of high-dose vitamin D3 on host immunity and other indices associated with recovery.

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