



11. Effects of Vitamin D Repletion and Maintenance Therapy on RA Characteristics and Quality of Life.

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Background/Purpose: Low Vitamin D levels are prevalent in Rheumatoid Arthritis (RA) and associated with higher disease activity and poorer quality of life (HRQL). We investigated the effect of vitamin D repletion and maintenance therapy in patients with low vitamin D levels.

Methods: 139 persons who met 1987 ACR RA criteria were enrolled in an RCT from 1/2009 – 4/2011. Exclusion criteria included hypercalcemia and hyperparathyroidism. Joint counts and patient and evaluator disease assessments were performed. Patients completed the HAQ, Pain VAS, Patient Global Assessment and SF12. 25(OH)D was assessed using the Diasorin radioimmunoassay; persons < 30 ng/ml were classified as deficient and were randomly assigned to receive either standard intensive therapy [50,000 IU ergocalciferol/week for 8 or 16 weeks till repletion (25(OH)D > 30 ng/ml) was achieved] + 16 weeks of maintenance therapy (50,000 IU ergocalciferol /month) or placebo for 16 weeks, followed by the vitamin D protocol. Results below are limited to the effects of vitamin D repletion and maintenance therapy, independent of original treatment assignment.

Results: Patients had a mean (SD) age of 52.5 (12.8) yr, RA duration of 9.8 (9.6) yr and BMI of 31.8 (6.8) kg/m² and were mostly female (83%), white (76%), well-educated (60% reported some college education) and non-smokers (61%). Of 73 who began repletion therapy, 58 were sufficient at 8 wks; 6 were sufficient at 16 weeks and 3 failed to achieve adequate levels. During maintenance, 62 people completed 8 wk and 61 completed 16 wk of therapy. Vitamin D increased an average of 71% (mean increase 17.3 [12.9]; range -22.4 – +57.8 ng/ml) during repletion then declined steadily during maintenance (see Table). Increases in 25(OH)D were inversely and moderately associated with baseline 25(OH)D ($r = -.43$; $p < .001$) but were not associated with age, sex, minority status, BMI, RA duration or smoking status. During repletion, the SF36 PCS and PF scores decreased significantly; no other changes in other PROs were statistically different at any timepoint.

Conclusion: Intensive repletion therapy modestly increased 25(OH)D levels in RA patients who were < 30 ng/ml at baseline, though levels fell throughout maintenance. Statistically significant decreases in physical health and function were reported though differences are below the MID; other PROs did not change over time. These data suggest that in RA patients with low vitamin D levels, standardized intensive vitamin D protocols appear to only modestly increase circulating levels of 25(OH)D with no change disease characteristics and HRQL.