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A randomized cohort study comparing the safety and effectiveness of high dose vitamin D to standard daily vitamin D therapy in children with vitamin D deficiency

Paul Tannous and **Craig Munns**
Children's Hospital Westmead NSW, Australia

Background and Objectives: Children with vitamin D deficiency are particularly susceptible to develop musculoskeletal complications. Vitamin D supplementation can correct vitamin D status (25-hydroxyvitamin D - 25OHD) and prevent nutritional rickets. Compliance with daily oral supplementation in children can be difficult to achieve. High dose vitamin D (stoss) therapy has been suggested to improve compliance and subsequently normalize vitamin D status. Consensus on optimal stoss doses is lacking and concerns regarding safety of stoss therapy in children remain. Our objective was to compare the effectiveness and safety of stoss versus standard therapy in treating vitamin D deficiency in children.

Methods: This was a randomized control trial that recruited children aged 2 to 16 years of age with vitamin D deficiency (25OHD <50nmol/L). Participants were randomized to receive either stoss (100,000 IU/ week for 4 weeks) or standard (5,000IU/day for 80 days) therapy. All participants were reviewed with a clinical exam at baseline, 4 weeks, and12 weeks after starting therapy. Measurement endpoints related to efficacy were 25OHD status and alkaline phosphatase levels, at baseline, 4 and 12 weeks. Endpoints related to toxicity included urinary calcium/creatinine ratio, hypercalcemia and 25-hydroxyvitamin D>250nmol/L. These were measured at baseline, 4 and 12 weeks. Compliance was measured by the number of empty vials returned.

Results: 135 children were enrolled in the study; 73 received stoss therapy and 62 received standard therapy. Children were from various ethnic backgrounds, predominantly made up by immigrant groups, with a median age of 9 years, and a BMI z score of 0.1. There was no significant difference in normalization of 25OHD status between the two groups. At 12 weeks, more than 80% of participants in both groups achieved sufficiency (25OHD> 75nmol/L). A similar result was seen with ALP, and PTH levels. Similarly, serum calcium and urinary calcium/creatinine ratio were largely within normal limits with no significant difference seen between the two groups. Compliance was similar in the 2 treatment groups.

Conclusions: We found no difference in efficacy or safety between 100,000 IU weekly for 4 weeks and standard daily therapy of 5,000IU in the management of vitamin D deficiency in children. Although simplifying treatment regimens has been known to improve medication compliance, this was not evident in our study. These results add to previous data supporting stoss as an effective and safe alternative for children. Long-term studies are needed to determine optimal dosing and monitoring schedules to maintain sufficient vitamin D levels throughout childhood.

paultannous@live.com