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FROM PILOT DATA TO CLINICAL TRIAL: OBSERVING THE EFFECTS OF VITAMIN D DOSAGE ON BONE QUALITY

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INTRODUCTION

The relationship between vitamin D and bone quality has been widely researched. Vitamin D is an essential component of normal bone health as well as calcium/phosphate metabolism. Despite significant research efforts, the optimum level of vitamin D intake remains a topic of controversy amongst industry experts. For example, the Institute of Medicine recommends between 600 and 800 international units (IU) per day [1, 2]. In contrast, both the osteoporosis Canada and the Endocrine Society guidelines recommend a wider range of daily dosages (400 to 2000 IU) [3, 4]. To date, there have been no dose-finding studies relating vitamin D intake and bone health. The absence of research in this area was the major motivation for both the pilot study and clinical trial presented in this abstract.

METHODS: PILOT DATA

Participants included in this study were patients from the Pure North S'Energy Foundation (PNSF). There were no exclusion criteria for this portion of the study. All participants received a series of blood draws from PNSF, which determined the vitamin D levels in their blood. These levels were then used to divide participants into four different groups: low vitamin D (<90 mmol/L), normal vitamin D (>90 mmol/L, <175 mmol/L), one time high vitamin D (>175 mmol/L for <6 months), and high vitamin D (>175 mmol/L for >6 months). Participants were then scanned using high resolution peripheral quantitative computed tomography (HR-pQCT, Scanco Medical), to analyze their bone micro-architecture in both the non-dominant tibia and radius. SPSS (version 21) was used to analyze the differences between groups with a One-Way ANOVA and a Tukey Post-Hoc test. Significance was set at $p<0.05$.

RESULTS: PILOT DATA

Overall, 113 participants were scanned using HR-pQCT while only 105 were included in the final analysis. Participants were on average 56 years old and 62% female. Both vitamin D ($p<0.01$) and calcium ($p<0.05$) were statistically different between groups using a One-Way ANOVA. Calcium was not controlled for the pilot study, but will be for the clinical trial. At the radius, cortical thickness ($p<0.05$) and cortical area ($p<0.05$) were significantly different across groups. Results from the Tukey Post-Hoc test showed that cortical thickness was significantly lower for low vitamin D compared to the high vitamin D group, as well as lower for the one-time high compared to the high vitamin D group. For cortical area, the one-time high group was significantly lower than the high vitamin D group. For the tibia, trabecular thickness was the only significant variable across groups ($p<0.05$), with low vitamin D being lower than the one time high vitamin D.

CONCLUSIONS: PILOT DATA

There were some bone parameters that were statistically different between vitamin D groups. Of these statistically different parameters, results differed between the radius and the tibia, as well as between cortical and trabecular bone. Most variables differed between the one-time high group and either the low or high groups. The only difference between the low and high groups was cortical thickness. This pilot data shows some interesting results, and the need for further, more controlled studies.

FUTURE WORK: CLINICAL TRIAL

This project will move forward in the form of a clinical trial entitled "A randomized double-blind study investigating dose-dependent longitudinal effects of vitamin D supplementation on bone health". The study will include approximately 300 healthy men and women between the ages of 55-70 years. Similar to the pilot study, participants will be assigned to one of three vitamin D dosages and HR-pQCT will be used to assess bone quality. Additional methods will be used to assess overall skeletal, physical and mental health.

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