

Improved healing of diabetic foot ulcers after high-dose vitamin D: a randomized double-blinded clinical trial

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Background: Chronic foot ulcers are a major cause of morbidity in diabetics with a life-time risk of chronic ulcers on the lower extremities of 25 %. Treatment is challenging and estimated 14 % have chronic leg ulcers for more than 10 years. Vitamin D deficiency is seen more commonly in diabetic patients with chronic foot ulcers, compared to non-diabetics as well as diabetics without foot ulcer.

Purpose / Aim of Study: To assess the efficacy of high-dose compared to low-dose Cholecalciferol vitamin D3 on healing of chronic diabetic foot ulcers.

Materials and Methods: We included diabetic patients with one or more ulcers of the foot for more than 6 weeks. Patients were randomly allocated to either a daily oral intake of high-dose (170 µg) or low-dose (20 µg) Cholecalciferol vitamin D3. Patients were seen in the outpatient clinic after 4, 12, 24, 36 and 48 weeks. At each visit, the ulcer was measured with a validated camera and the area (cm²) was calculated. Patients and assessors were blinded to treatment allocation. All patients were followed for 48 weeks or until wound healing or surgical treatment.

Findings / Results: 64 ulcers in 48 patients (24 in each group) were included in the analysis. 41 ulcers were followed until healing or 48-week follow-up and 20 ulcers were surgically treated during the study period. Three patients were lost to follow-up. The intention-to-treat analysis showed a significantly higher rate of ulcer healing in the high-dose group with 21/30 (70%) compared to 12/34 (35%) healed ulcers in the low-dose group ($p = 0.012$). Median ulcer reduction at final follow-up was 100% [IQR: 72 to 100] compared to 57% [IQR: -28 to 100.0]. Furthermore, we found a significant effect of high-dose Cholecalciferol vitamin D3 in the repeated measures analysis of variance using square-root-transformed ulcer area as dependent variable ($p = 0.014$).

Conclusions: High-dose Cholecalciferol vitamin D3 is efficient, compared to low-dose Cholecalciferol vitamin D3, in promoting wound healing in diabetic foot ulcers.