Active vitamin D [1,25(OH)2D3] deficiency may be risk factor for cardiovascular disease (CVD) and renal disease. Retrospective cohort studies in type 2 diabetes (T2DM) patients with stage 3/4 chronic kidney disease (CKD) have demonstrated that calcitriol treatment is associated with reduced CVD mortality. Aortic pulse wave velocity (Ao-PWV) is an independent predictor of CVD and progression of renal disease. There is limited randomised controlled trial data in patients with diabetes and CKD on the effect of active vitamin D treatment on Ao-PWV.

We performed a 48 week duration single centre randomised double blind parallel group placebo controlled intervention trial, examining the impact of calcitriol 0.25 mcg od as compared to placebo. Patients with T2DM and clinical evidence diabetic kidney disease and an estimated glomerular filtration rate (eGFR) between 30-59 ml/min and raised intact parathyroid hormone (iPTH) level >30 pg/ml were eligible. Primary endpoint was change in Ao-PWV measured by applanation tonometry (Sphygmocor system). Secondary endpoints included albuminuria (measured by urine albumin excretion rate-AER), central arterial blood pressure, serum calcium, phosphate levels, eGFR, and iPTH.

In total 127 (male 70%) patients were randomised to calcitriol (n=64 or placebo n=63) and eligible for analyses. Baseline, mean ± standard deviation, values for selected variables were: age 64 ± 7.8, eGFR 43.2 ±20.1 ml/min, SBP 146.2 ±19.9 mmHg , DBP 76.6±11 , Ao-PWV 11.6±3.2 m/s, iPTH 61.6±34 pg/ml and AER median (interquartile range) was 50.51 (11.5 to 188.6) mcg/min. There were no significant deference's between the two groups in baseline clinical or biochemical indices.
Following treatment with calcitriol there was no significant mean (95% confidence interval-CI) change in Ao-PWV as compared to placebo of 0.05 m/s (-0.68 to 0.78) vs 0.23 m/s (-0.46 to 0.93) with a between treatment mean (95% CI) difference for Ao-PWV of 0.19 (-0.81 to 1.19) m/s p=0.71.
No statistically significant effect of calcitriol treatment was observed on central arterial pressures or albuminuria or eGFR in unadjusted analyses. Serum calcium and phosphorus levels during the study did not differ between groups. Overall calcitriol was well tolerated with no treatment related serious adverse effects reported.
In T2DM patients with stage 3 CKD, 48 week treatment with calcitriol as compared to placebo does not improve Ao-PWV.