Impact of Dialysate Calcium Concentration on Intradialytic Left Ventricular Systolic Function and Marker of Vascular Calcification: A Randomized, Double-blinded, Non-Inferiority Study (CALLISTO Study)

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**Background:** Intradialytic hypotension (IDH) is a serious complication during hemodialysis (HD). High dialysate calcium (Ca) concentration is generally prescribed in patients who are at risk for IDH since it is believed that high dialysate Ca can improve left ventricular ejection fraction (LVEF). However, an evidence of LVEF improvement with high dialysate Ca is scarce as well as it may increase risk of vascular calcification that may contribute to high mortality in dialysis patients.

**Objectives:** To test the hypothesis that low dialysate Ca is not inferior to high dialysate Ca, with the use of a margin of 5% for the changes of LVEF during HD with low dialysate Ca as compared to high dialysate Ca.

**Methods:** A single center, randomized, double-blinded, non-inferiority study was conducted. ESRD patients undergoing chronic HD were randomized into 2 groups: high dialysate Ca (1.75 mmol/L, Ca-1.75 group) and low dialysate Ca (1.25 mmol/L, Ca-1.25 group). The primary endpoint was the changes of LVEF, comparing between predialysis and 3-4 hours after dialysis on the day of randomization. The secondary endpoint was episodes of IDH and changes of biomarker of inflammation, i.e. c-reactive protein (CRP) and vascular calcification, i.e. fibroblast growth factor-23 (FGF-23) during 6-month period.

**Results:** Seventy-eight ESRD patients were included (38 in Ca-1.25 group and 40 in Ca-1.75 group). Mean changes of LVEF during dialysis session in the Ca-1.25 group was +4.2 ± 6.8% vs +2.3 ± 6.5% in the Ca-1.75 group (difference was +1.9 ± 1.5, 95% CI -1.1 to +5.0, p=0.211). Mean changes of systolic blood pressure (SBP) in the Ca-1.25 group was -3.2 ± 20.5 mmHg vs +7.2 ± 17.6 mmHg in Ca-1.75 group (p=0.019). At the completion of this abstract, 20 patients (52.6%) in the Ca-1.25 group and 22 patients (55.0%) in the Ca-1.75 group completed 6-month follow-up. Episodes IDH were higher in the Ca-1.25 group (178 episodes from 1,731 dialysis sessions (10.3%) vs 121 episodes from 2,037 dialysis sessions (5.9%) in the Ca-1.75 group, p <0.001). Compared to the Ca-1.75 group, CRP reduction was higher in the Ca-1.25 group (p=0.015). However, changes of FGF-23 levels were not different between the two groups (p=0.743).

**Conclusions:** Improvement of LVEF during HD with dialysate Ca of 1.25 mmol/L is not inferior to dialysis with dialysate Ca of 1.75 mmol/L. Although IDH is lower in the Ca-1.75 group, CRP levels were significantly increased, whilst, changes of FGF levels were not different between groups.

**Keywords:** Dialysate calcium concentration, intradialytic hypotension, LVEF, CRP, FGF-23