



There was no significant difference ( $P=.76$ ) between placebo and ergocalciferol in the change in EPO dose or change in PTH ( $P=.60$ ). In addition, there were no significant changes in calcium, phosphorous, calcitriol dose, phosphate binder use, cinacalcet use, or CRP levels or significant differences between groups in all-cause hospitalization, cardiovascular hospitalization, infectious hospitalization, total infections, falls, and fracture events.

The only significant difference between groups was in doxercalciferol; the change in micrograms/treatment/month for the ergocalciferol group was 0.21 (95% CI, 0.10 to 0.31) and for the placebo group was 0.04 (-0.06 to 0.15;  $P=.02$ ). However, Dr Miskulin did not consider this to be clinically significant.

Although it was the largest randomized controlled trial of vitamin D supplementation in patients on dialysis, this study was subject to limitations, including a high percentage of black patients ( $n=160$ ), who have lower total 25(OH)D levels than whites [Powe CE et al. *N Engl J Med.* 2013], although in a subgroup analysis, no differences by race were found for any outcome.

Supplementation with 25(OH)D to achieve levels  $\geq 30$  ng/mL in patients on dialysis is safe, but in this short, underpowered study, it does not appear to offer any benefits.

## Fluency Plus ePTFE Stent Superior to PTA for In-stent Restenosis

Written by Emma Hitt Nichols, PhD

Placement of a Fluency Plus stent graft after percutaneous transluminal angioplasty (PTA) was superior to PTA alone in treating in-stent restenosis for restoring access circuit tertiary patency (ACPP) at 6 months. Alexander Yevzlin, MD, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin, USA, presented data from the FLUENCY PLUS Endovascular Stent Graft for In-stent Restenosis trial [RESCUE; NCT01257438].

In-stent restenosis occurs in about 54% to 59% of cases and is the primary location of restenosis in the access circuit [Chan MR et al. *Hemodial Int.* 2009; Vogel PM, Parise C. *J Vasc Interv Radiol.* 2004]. Yet there is no evidence-based recommendation for the treatment of in-stent restenosis. However, expanded polytetrafluoroethylene (ePTFE) stent grafts may offer a potential treatment option for in-stent restenosis. The purpose of the RESCUE study was to determine the safety and efficacy of the Fluency Plus ePTFE stent.

In the multicenter RESCUE trial, 265 patients with in-stent restenosis were randomly assigned to receive PTA

or PTA plus the Fluency Plus stent graft. Patients were included in the study if they had atriovenous (AV) fistulae or AV graft, they had peripheral or central vein stenoses, the target lesion was located in the restenosed bare metal stent, the target lesion was  $\leq 10$  cm in length, and the reference vessel diameter was 5 to 12 mm. Patients were excluded if the target lesion had a corresponding thrombosis within 7 days of the procedure, the graft or fistula was infected, a pseudoaneurysm was present in the target lesion, the device was placed across a  $>90^\circ$  angle, and the lesion was located across an elbow joint, cephalic arch, superior vena cava, or the cannulation zone. Patients were followed for 24 months and received a mandatory angiogram at day 90.

The primary efficacy end point of the RESCUE trial was ACPP at 6 months. The primary safety end point was freedom from any localized or systemic adverse events related to the AV access circuit that required additional intervention, hospitalization or prolonged hospitalization, or death.

PTA plus the Fluency Plus stent graft was statistically superior to PTA alone, with 16.7% of patients in the Fluency Plus arm achieving ACPP at 6 months compared with 3% in the PTA-only arm ( $P<.001$ ). There was no difference in outcomes based on access type, and there was no difference in outcomes between AV graft or fistula. However, there was a significantly greater benefit for patients with central lesions compared with peripheral lesions at 6 months ( $P=.023$ ). The rate of freedom from binary restenosis at the mandatory angiogram at 90 days was 81% and 25% in the Fluency Plus and PTA-only arms, respectively ( $P<.001$ ). In the intention-to-treat analysis, there was no significant difference in the primary safety end point of freedom from safety events up to 30 days, with a rate of 97% in both arms.

In conclusion, Dr Yevzlin stated that, in his opinion, the data from the RESCUE trial indicate that PTA with placement of the Fluency Plus stent graft was superior to PTA alone for the primary end point of ACPP, as well as binary restenosis  $>50\%$ , with similar safety outcomes.

## MSCs Do Not Reduce Time to Recovery in Postcardiopulmonary Bypass AKI

Written by Lynne Lederman

Acute kidney injury (AKI) is a major complication of cardiac surgery and can progress to chronic kidney disease and death. AKI rates in cardiac surgery have been increasing, and treatment strategies are needed since post-AKI recovery of kidney function is associated with