Cardiac Remodeling Following Ligation of Arteriovenous Fistula in Stable Renal Transplant Recipients: a Randomised Controlled Study

DISCUSSION

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The 93 patients represent which percentage of alive, stable renal transplant recipients in the region where the study took place? Which criteria determined the selection of these 93 patients for assessment of eligibility?

Since the analysis was Intent-to-Treat, how did the Investigators handle the 10 (16%) patients who did not undergo a second CMR?
Results

- **Primary Outcome**: mean decrease of 22.1 g (95% CI, -29.1 to -15.0) in LV mass in the AVF ligation group compared to a rise of 1.2 g (95% CI, -4.8 to 7.2) in the control group (p< 0.001)

- This translates into a 14.7% decrease in LVM 6 months after AVF ligation

- **Secondary Outcomes**: Compared to controls, the AVF ligation group had significant decreases in:
  - LEDV (mL): p< 0.001
  - LVESV (mL): p< 0.01
  - RVEDV (mL): p<0.001
  - RVESV (mL): p<0.01
  - LA area (cm²): p<0.001
  - LAV (mL): p < 0.001
  - RA area (cm²): p< 0.001
  - PA peak velocity (m/sec): 0.07
  - NT-proBNP (pg/mL); p< 0.01
  - CO?

No significant change in eGFR at follow-up comparing AVF ligation versus controls.
In the Australian and New Zealand Clinical Trial Registry, the following statement can be found regarding ACTRN1261300130274:

“Based on a pilot data, the sample size is estimated to 40 subjects in each group to give a statistical difference of 9.7% in LV mass with a power of 80%.

Based on this statement, how did the sample size decrease from 80 to 64 study subjects? It would be very interesting to know how the study’s sample was recalculated.
Observations - Clinical

- Did a 14.7% reduction in the surrogate end-point of LV mass translate into clinically meaningful outcomes (HF events, QOL measures, mortality)?

- Reduction in LV mass appears to be driven entirely by smaller LV volumes without reported decreases in wall thickness: do the consequences of a higher LV mass differ if the increase is due to changes in cardiac volumes versus changes in wall thickness?

- AVF flow at baseline was higher in the intervention than in the control arm (1,821 mL/min vs. 1,375 mL/min: p=0.04)-was the effect of AVF ligation on LV mass magnified in the intervention group because of the elimination of a significantly higher AV flow?

- It would be very interesting to know:
  - data on variables known to impact the fate of renal allografts, including organ ischemia time, incidence of delayed allograft function, type of donor (living versus deceased)
  - whether BP control was similar in the two arms of the study.
  - which medications did patients receive to control BP in the two arms of the study
  - which immunosuppressive regimens were used in the two arms of the study
The trial by Stokes MB and Colleagues is an important and novel proof of concept study that can support larger RCTs powered for clinically meaningful outcomes.

Thank you!