Lesson About Hemodialysis Adequacy from the HEMO Study

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In the early 90's, the mortality of ESRD patients in the United States was approximately 220 deaths per 100 patient years. This rate was higher than the much of Western Europe and Japan.

Parallel information based on a survey of hemodialysis patients, only about 45% of patients received an adequate hemodialysis dose defined as a urea reduction ration of ?65%. A substantial body of observational data, and extrapolation from the National Cooperative Dialysis Study along with other smaller intervention trials suggested that higher doses of hemodialysis expressed as urea clearance or flux of larger molecular weight solutes will improve patient survival. Towards validating this hypothesis, between 1994 and 2002, a multi-centered, randomized controlled trial was performed in the U.S. that enrolled a total of 1,846 prevalent hemodialysis patients. Using a recruit to replace randomization strategy, approximately 900 patients were randomized using a 2×2 factorial intervention to receive an equilibrated (e) Kt/V of 1.05 and flux for β_2-microglobulin <10 or >20 mL/min. and received 5 years of intervention.

The study design offered 84% power to detect 25% reduction in the primary outcome of mortality rate. The secondary outcomes were 1st cardiac hospitalization, infectious hospitalization, declining serum albumin concentration, all non-access related hospitalizations, or all-cause mortality. An intent to treat analysis of the primary outcomes was performed; Cox regression of survival after randomization was the analytic method used for the primary outcome.

Patients incident to the study were 58±14 (SD) years old; 56 % were female; 63% black; 69% had hypertension; 45% had diabetes mellitus; and 80% had cardiac disease. Separation of the intervention groups was achieved: 1.16 vs.1.53 for eKt/v and 3.4 vs. 33.8 mL/min for flux. In comparison to the low Kt/V group, patients treated to higher dialysis doses had an adjusted relative risk of death of 0.96 (p=0.53). In comparison to the low flux group, patients treated using high flux dialyzers had an adjusted relative risk of death of 0.92 (p=0.23). In summary, patients who received a hemodialysis dose higher than the minimum recommended or who used high-flux filters neither lived longer nor had fewer hospitalizations than patients who received the standard dose (Kt/V ~1.2) or used low-flux dialyzers. The results support clinical practice guidelines from the U.S. National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (K/DOQI).