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well-being and survival. I dare suggest that the recent Frequent Hemodialysis Network 2nd arm trial—the FHN(2) trial (3)—of extended-hour home hemodialysis versus conventional hemodialysis is in the same category and risks leaving a similar misinterpretation. Yet, all three are RCT analyses…so, they must be right, eh?

Such is the aura of the epithet “RCT” that any conclusion drawn by an RCT becomes “lone” in the blink of an eye. Like apologies that follow media errors, printed much later, recorded in small print, appearing on page 47 near the ordinary section; the error for which it “apologizes” long ingrained, dissenting opinions of RCT results either are dismissed or appear too late to alter the RCT “message.” This effect is amplified if the RCT in question has been long awaited and widely anticipated (advertised) to provide the “authoritative answer”—as was the case with the FHN trials. But although FHN(2) purported to yield an answer, it did not.

Even more concerning, now that RCTs have gathered such a bullproof aura that legislators and funding agencies now structure practice regulations and funding models based on their outcomes, an incorrect conclusion from FHN(2) risks ensnaring a further grave dialysis misstep.

Twardowski and Mira (4) nicely summarized the complexity—no, the impossibility—of achieving fair trial conduct and believable outcomes in an area as fraught as modality choice, wherein multiple competing comorbidities, socioeconomic circumstances, and expectations affect every dialysis patient differently. To be honest, dialysis patients are just not a homogenous group, and homogeneity of comparable groups is part and parcel of RCT selection and study.

There are now 60 or more years of worldwide accumulated experience in home hemodialysis, most of it outside the United States, with the past 15 years focusing on the two more recent iterations of home hemodialysis treatment—extended-hour and high-frequency (usually nocturnal) home hemodialysis, and short daily home hemodialysis. Carl Kjellstrand, a greatly respected savant of hemodialysis, compiled a lexicon of home hemodialysis publications appearing before 2000. This list, even then, exceeded 600 articles and abstracts; since then it has more than doubled. Although all these were observational and cohort studies, they were nonetheless studies by reputable experts in this field. Not one recorded a lesser outcome for home care. Nor have any since. Yet, given that these were criticized for selection bias and a range of other “shortcomings,” an RCT was demanded to settle the disquiet that these articles supporting home hemodialysis were somehow selling a lie.

Although I commend the authors of FHN(2) for their effort, a horrendous task gamely and honestly attempted, their fatally flawed study has seemingly swept aside this accumulated knowledge with one hopelessly underrecruited and underpowered RCT. FHN(2) suffered from all the recruitment biases it sought to exclude. Fewer than 35 percent of the subject numbers required by pre- trial statistical and power analyses were recruited, and they were resistant to randomization to center-based conventional care that the rules were altered in midtrial to permit the conventional arm to receive dialysis at home, where survival is twice that of in-center care (5). Even then, only 75 percent of those randomized to the home nocturnal arm performed their dialysis treatments as required by the trial design. Despite all this, the conclusion reported that extended-hour, high-frequency nocturnal home dialysis was no better than standard conventional hemodialysis.

A fairer conclusion might have been that despite a clear trend to near-significance in favor of home-extend- ed hour and high-frequency dialysis from only a third of the predicted number of study participants, the trial was a design, recruitment, and statistical failure. A more honest conclusion should have “fessed up to this. An ex-
cellent critique puts this brave, but failed, RCT into its proper perspective (6).

Do we need another RCT to resolve the issue? I contend, no. Ask yourself this question: has there ever been an RCT between transplantation and dialysis? No. If not, why not? It is simply because we know we can never fairly randomly assign patients to transplantation versus dialysis, any more than we can fairly randomize to one type of dialysis versus another. Yet, we universally aknowledge that “transplantation is the best therapy” and that “transplantation survival is better.” Will yet another RCT of dialysis modality add anything further? No, it will not.

References


Home Dialysis

Clinical Advantages of Home Hemodialysis

By Christopher T. Chan

Home hemodialysis (HHD) has emerged as an im-
portant alternative treatment option for patients
with end stage renal disease. The renaissance of HHD is
based in part on several established and potential clini-
cal benefits. In addition, HHD also acts as a conduit
for intensive hemodialysis, which is otherwise not feasible
in the context of dialysis centers. Various considerations
and implications of establishing and implementing HHD
have already been covered in this issue of Kidney News.

There are now 60 or more years of worldwide accumulated experience in home hemodialysis, most of it outside the United States, with the past 15 years focusing on the two more recent iterations of home hemodialysis treatment—extended-hour and high-frequency (usually nocturnal) home hemodialysis, and short daily home hemodialysis. Carl Kjellstrand, a greatly respected savant of hemodialysis, compiled a lexicon of home hemodialysis publications appearing before 2000. This list, even then, exceeded 600 articles and abstracts; since then it has more than doubled. Although all these were observational and cohort studies, they were nonetheless studies by reputable experts in this field. Not one recorded a lesser outcome for home care. Nor have any since. Yet, given that these were criticized for selection bias and a range of other “shortcomings,” an RCT was demanded to settle the disquiet that these articles supporting home hemodialysis were somehow selling a lie.

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References