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Session Topic : -

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The Perspective of Pragmatic Clinical Trial in PRIDE Study

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Background The optimal dialysis regimen for older adults with end-stage kidney disease (ESKD) remains uncertain. Standard thrice-weekly hemodialysis (HD) may not reflect the needs or tolerability of elderly patients, especially those with residual kidney function (RKF). The PRIDE study was designed as a pragmatic randomized controlled trial (RCT) to evaluate real-world effectiveness—rather than efficacy—of twice-weekly HD using an incremental approach, as compared to conventional thrice-weekly HD. A pragmatic trial approach was essential to accommodate clinical diversity, physician judgment, and individual patient needs often encountered in routine care. **Methods** This multicenter, open-label, pragmatic RCT recruits 428 incident HD patients aged ≥ 60 years with >500 mL/day urine output. Participants are randomized to either a twice-weekly HD group (incrementally intensified as needed) or a standard thrice-weekly group. The study is being conducted across 18 dialysis centers in Korea, reflecting diverse real-world settings. The primary outcome is the all-cause hospitalization rate over 24 months. Secondary endpoints include dialysis-related hospitalizations, mortality, frailty, quality of life, and cost-effectiveness. Physicians retain autonomy in adjusting dialysis prescriptions based on patient status, aligning the study with actual clinical practice. **Results** Although the study is ongoing (completion anticipated in May 2026), its design already highlights the feasibility and value of integrating pragmatic methodologies in nephrology research. Flexibility in treatment, heterogeneous settings, and clinically relevant endpoints ensure the generalizability and utility of the findings for policy and practice. **Conclusion** The PRIDE study represents a model of pragmatic clinical research that prioritizes external validity, clinical relevance, and applicability to everyday practice. It is expected to provide essential evidence for optimizing dialysis regimens in older adults, potentially supporting a shift away from rigid treatment protocols toward more individualized, evidence-informed care.

Keywords: elderly, hemodialysis, hospitalization, pragmatic, RCT