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Effect of Expanded Hemodialysis with Theranova Dialyzer on Preservation of Residual Kidney Function: The THREAD Randomized Controlled Trial

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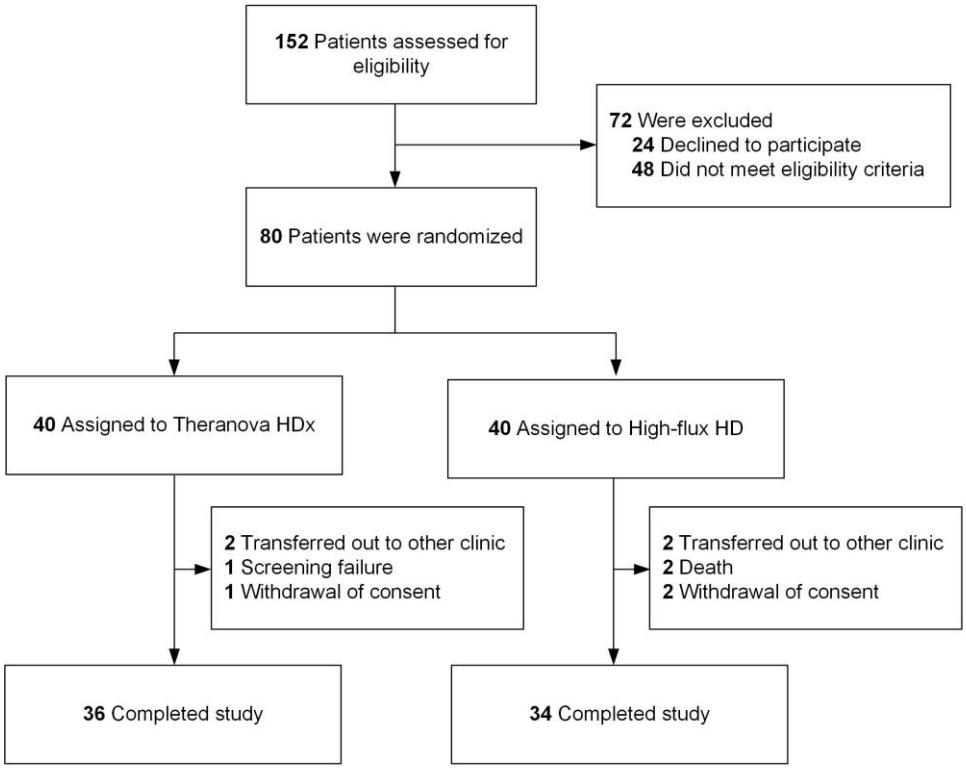
Objectives : Expanded hemodialysis (HDx) using a medium cut-off dialyzer can improve the clearance of middle-molecular uremic toxins compared to conventional hemodialysis. However, its effect on residual kidney function (RKF) remains unclear. This study evaluated the effect of HDx on RKF preservation in incident hemodialysis patients.
Methods : Patients who initiated hemodialysis with RKF were randomized to receive dialysis with either an HDx with Theranova 400 (Baxter) or a high-flux dialyzer with a similar surface area over 12 months (Figure 1). The primary outcome was a change of RKF for 12 months. Secondary outcomes were changes in 24-hour urine volume, middle molecules, and kidney injury markers.
Results : Eighty hemodialysis patients (mean age: 62.7 ± 11.9 years; 65.0% male) were randomized. Over 12 months, Theranova group showed a significantly smaller decline in RKF compared to the high-flux group (-1.20 mL/min [interquartile range {IQR}, -2.29, -0.22] vs. -2.24 mL/min [IQR, -3.62, -0.46], P=0.019) (Figure 2). There was no significant difference in 24-hour urine volume at 12 months. However, Theranova maintained a greater 24-hour urine volume until 9 months compared to the high-flux dialyzer. After 12 months, Theranova group showed a significantly lower increase in β2-microglobulin. Additionally, the increase in kidney injury markers, such as IGFBP-7 and KIM-1, was significantly reduced in the Theranova group compared to the high-flux group. The reduction ratio for TNF-α and GDF-15 was higher in the Theranova group than the high-flux group. No significant differences were observed in hospitalization rate or mortality between the two groups.
Conclusions : HDx using the Theranova dialyzer has preserved the decline in RKF compared to the high-flux dialyzer of similar size in newly initiated hemodialysis patients. The removal of middle molecules by HDx was associated with reduced kidney damage in the early stages of dialysis. Clinical Trial Registry: Theranova Versus High-flux Dialyzer on Preservation of Residual Renal Function(THREAD); NCT04211571.

Figure 1. Flow chart_231005.jpg



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