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Efficacy and Safety of the PUREMA Polyethersulfone Membrane in Hemodialysis: A Multicenter, Randomized, Cross-Over Study

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Objectives : The prevalence of end-stage kidney disease (ESKD) in South Korea has nearly doubled over the past decade, with hemodialysis (HD) as the predominant kidney replacement therapy. Despite increasing clinical demand, dialysis-related medical devices are fully dependent on imports. A national research initiative has led to the development of a domestically manufactured high-flux dialyzer using a polyethersulfone membrane with established biocompatibility and structural integrity. This study aimed to evaluate the clinical non-inferiority and safety of the newly developed dialyzer compared to an imported high-flux dialyzer in Korean ESKD patients.
Methods : In this multicenter, randomized, cross-over clinical trial, 48 patients on maintenance HD were randomized to receive either the test or control dialyzer for four weeks, followed by crossover to the alternative device. The primary efficacy endpoint was the urea reduction ratio (URR). Secondary endpoints included single-pool Kt/V (spKt/V) and reduction ratios of small and middle-molecule solutes. Safety endpoints included adverse events and intradialytic complications.
Results : Paired t-tests showed statistically significant differences in spKt/V (1.5 ± 0.3 vs. 1.6 ± 0.3; P = 0.002) and URR (72.5 ± 6.3% vs. 73.7 ± 6.6%; P = 0.001) between the two dialyzers; however, non-inferiority of the test dialyzer was demonstrated based on the pre-defined clinical margin. The test dialyzer also showed significantly higher reduction ratios for middle-molecule solutes, including cystatin C (56.6% vs. 37.8%), β2-microglobulin (56.8% vs. 50.8%), myoglobin (31.8% vs. −9.5%), and prolactin (28.5% vs. −3.4%) (all P < 0.001). There was no significant difference in interleukin-6 clearance (P = 0.854). No unexpected safety concerns or serious adverse device effects were observed.
Conclusions : The domestically developed high-flux dialyzer demonstrated non-inferior dialysis adequacy and superior middle-molecule clearance compared to a commercially available product, supporting its clinical use in maintenance hemodialysis.

Figure 1.jpg

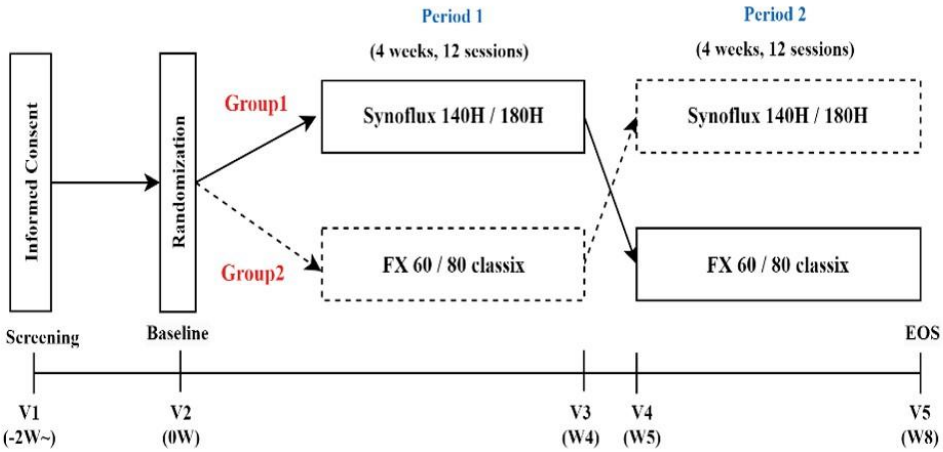

Figure 1.jpg

Table 3. Comparison of primary outcomes and assessment of non-inferiority

	Synoflux	Control	P value	Mean Difference	95% CI
spKt/V	1.5 ± 0.3	1.6 ± 0.3	0.002	-0.062	-0.100, -0.233
URR (%)	72.5 ± 6.3	73.7 ± 6.6	0.001	-1.293	-2.008, -0.580

Table 4. Comparison of Middle-Size Molecule Clearance

Reduction Ratio (%)	Synoflux	Control	P value
Cystatin C	56.6 (53.6-62.8)	37.8 (32.9-44.8)	<0.001
B2-Microglobulin	56.8 (51.3-66.1)	50.8 (43.4-58.2)	<0.001
Myoglobin	31.8 ± 8.6	-9.5 ± 10.1	<0.001
Prolactin	28.5 (23.9 – 36.6)	-3.4 (-13.4 - 3.0)	< 0.001
Interleukin-6	- 10.2 (-26.4 – 9.9)	-9.0 (-20.0 – 9.1)	0.854