Study results

Safety : Laboratory markers and adverse events

- **Albumin** 등의 biochemical marker는 베이스라인 및 12주 차에 **두 그룹 간에 차이를 보이지 않았으며, 초여과량과 투석의 적정성 역시 유사한 결과**를 보였습니다.[1]
- 12주의 연구 기간 동안, 심혈관 질환, 사망, 혈압 감소 등 투석막의 변경이 필요한 **중대한 이상반응은 발생하지 않았습니다.**[1]

Comparisons of the changes in biochemical markers and dialysis adequacy in both dialysis groups[1]

	Baseline			12 weeks		
	MCO (n=24)	HF (n=25)	P	MCO (n=24)	HF (n=25)	P
Hemoglobin (g/dL)	10.6 ± 0.9	10.7 ± 1.1	0.859	10.9 ± 0.9	11.0 ± 1.0	0.697
Albumin (g/dL)	4.11 ± 0.38	4.06 ± 0.33	0.635	3.98 ± 0.27	4.04 ± 0.33	0.450
Creatinine (mg/dL)	10.8 ± 2.5	9.6 ± 2.5	0.093	11.5 ± 2.9	10.0 ± 3.1	0.086
Phosphate (mg/dL)	3.88 ± 0.93	4.05 ± 1.08	0.561	4.08 ± 1.39	4.36 ± 1.35	0.471
BUN (mg/dL)	60.3 ± 16.1	63.2 ± 18.7	0.565	65.5 ± 18.8	60.2 ± 18.2	0.318
Total cholesterol (mg/dL)	125.1 ± 27.7	126.4 ± 28.3	0.874	128.1 ± 31.4	121.6 ± 33.8	0.491
HDL cholesterol (mg/dL)	41.8 ± 12.1	44.1 ± 12.4	0.510	44.7 ± 14.2	43.1 ± 15.7	0.706
Ultrafiltration (L)	1.99 ± 0.84	1.98 ± 0.93	0.964	2.16 ± 0.82	1.98 ± 0.86	0.444
Single-pool Kt/V	1.61 ± 0.22	1.67 ± 0.22	0.296	1.64 ± 0.18	1.68 ± 0.22	0.411

Adapted from Lim JH, et al. 2020.

BUN, blood urea nitrogen; HDL, high-density lipoprotein; HF, high-flux; MCO, medium cut-off

Reference 1. Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Sci Rep. 2020 May 8;10(1):7780.

KO/MG209/20-0008

Baxter

서울시 종로구 종로1 교보생명빌딩 10층 1001호 **Tel** 02. 6262. 7100 **Fax** 02. 6272. 7101

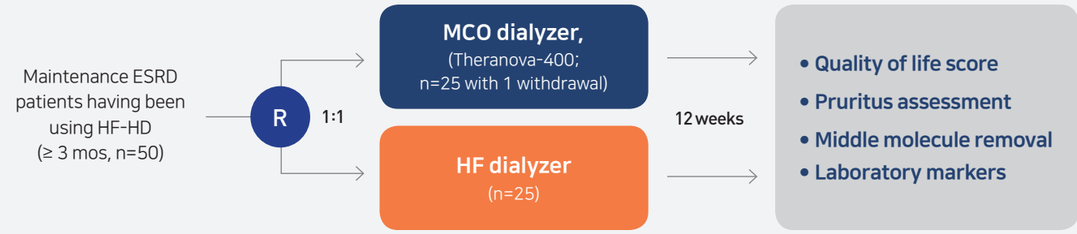
Baxter

Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients

Lim JH, et al. Sci Rep. 2020 May 8;10(1):7780.

Study design

Medium cut-off (MCO) 투석막이 혈액투석 환자의 삶의 질 향상에 미치는 영향을 High-flux (HF) 투석막과 비교 평가한 연구*



- 두 그룹 간 균형적인 베이스라인 환자 특징(age, gender, body mass index, dry weight, daily urine volume, vascular access, baseline dialyzer, dialysis vintage 등)을 보였습니다.[1]

*A randomized, prospective, controlled, open-label, phase 4 trial to investigate the effect of an MCO dialyzer on the improvement of QOL in maintenance hemodialysis patients. Patients treated with maintenance HD at the Kyungpook National University Hospital were enrolled and randomized starting in July 2018, and the study was completed in January 2019. Forty-nine HD patients with high-flux dialysis were randomly assigned to either an MCO (Theranova 400, Baxter) or a high-flux dialyzer and completed the study. The mean age of the MCO group patients switched from a high-flux membrane was 62.2 ± 13.7 years, and 75.0% were men. The high-flux group patients had a similar mean age and percentage of male participants (63.8 ± 15.2 years and 60.0%, respectively). QOL was assessed at baseline and after 12 weeks of treatment using the Kidney Disease Quality of Life Short Form-36, and pruritus was assessed using a questionnaire and visual analog scale. The reduction ratios of middle molecules were also evaluated.

Conclusions

혈액투석 환자에 **MCO 투석막의 사용은 고유량(HF) 투석막에 비하여 신체적 삶의 질 범주† 및 요독 가려움증과 같은 patient reported outcome을 개선**시킬 수 있습니다.

더불어 **MCO 투석막의 사용은 대표적인 큰 중분자 요독 물질인 Kappa 및 lambda FLC (유리형 경쇄)의 제거율 및 투석 전 혈장 농도 수치를 유의하게 낮추는 결과**를 보였습니다.
또한, 추적 기간 이후 두 그룹 (MCO 사용군 및 HF 사용군) 간에 **혈청 알부민 수치는 유의미한 차이를 보이지 않았습니다.**[1]

† physical functioning and role-physical component domains of the QOL
ESRD, end-stage renal disease; HD, hemodialysis; mos, months; QOL, quality of life

Study results

Quality of life : Kidney Disease Quality of Life-Short Form (KDQOL-SF) scores

- KDQOL-SF questionnaire의 26개의 항목 중, **MCO군은 신체적 기능 및 신체적 역할 영역**에서 HF 대비 **더 나은 QOL 결과**를 보였습니다.[1]

Quality of life questionnaire scores at baseline and 12 weeks[1]

	Baseline			12 weeks		
	MCO (n=24)	HF (n=25)	P	MCO (n=24)	HF (n=25)	P
Physical functioning	72.1 ± 23.7	59.4 ± 28.3	0.096	75.2 ± 20.8	59.8 ± 30.1	0.042
Role-physical	56.3 ± 39.2	44.0 ± 40.4	0.287	61.5 ± 37.6	39.0 ± 39.6	0.047

Adapted from Lim JH, et al. 2020.

Values are shown as the mean ± standard deviation

Quality of life : Assessment of uremic pruritus

- 12주 차 MCO군에서 HF군 대비 **아침 소양증 분포 평균점수* 및 수면 중 긁는 행위의 빈도가 통계적으로 유의하게 낮았습니다.**[1]

Quality of life questionnaire scores at baseline and 12 weeks[1]

	Baseline			12 weeks		
	MCO (n=24)	HF (n=25)	P	MCO (n=24)	HF (n=25)	P
Distribution						
Morning	1.42 ± 0.58	1.48 ± 0.71	0.736	1.29 ± 0.46	1.64 ± 0.64	0.034
Sleep disturbance						
Frequency of scratching during sleep	0.38 ± 0.92	0.24 ± 0.72	0.571	0.25 ± 0.53	1.00 ± 1.47	0.023

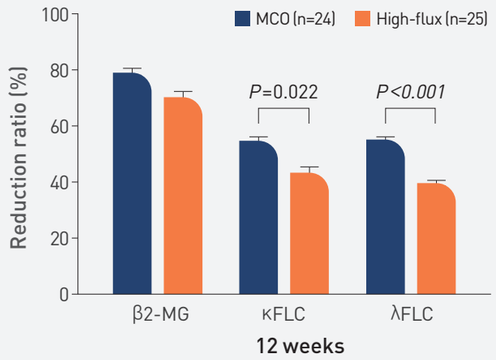
Adapted from Lim JH, et al. 2020.

*Uremic pruritus was assessed using the scoring system modified by Pauli-Magnus. Itching at less than two sites, more than two sites, and generalized itching received 1, 2, and 3 points, respectively.
HF, high-flux; MCO, medium cut-off; QOL, quality of life

Efficacy : Reduction ratios of middle molecules

- 중분자 물질들에 대한 제거율 분석 결과, MCO군은 12주 차에 HF군 대비 **대표적인 큰 중분자 요독 물질인 κFLC 및 λFLC의 제거율이 유의하게 더 높았습니다.**[1]

Reduction ratio of middle molecules at 12 weeks[1]



Reduction ratio of uremic retention solutes at 12 weeks[1]

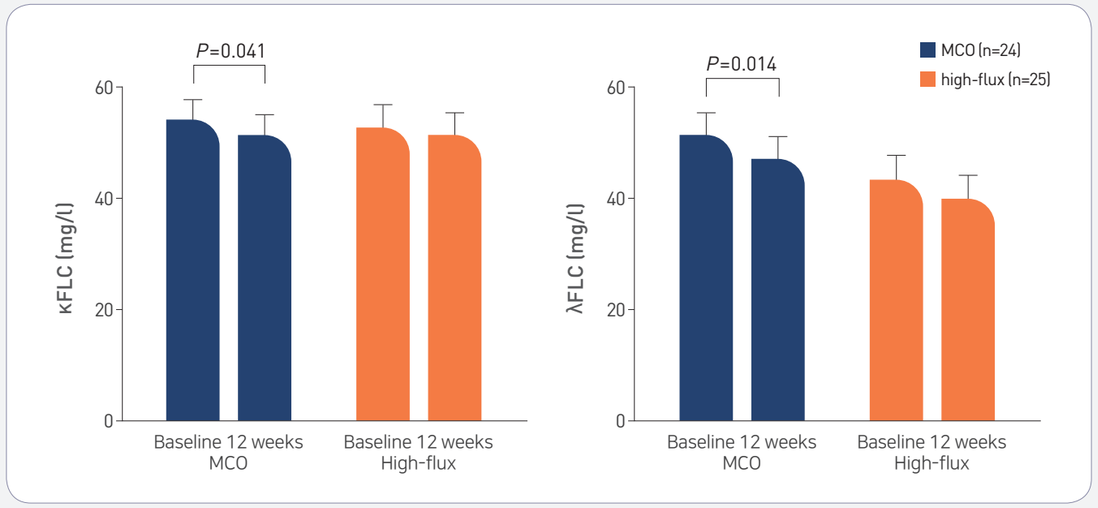
Reduction ratio (%)	MCO	HF	P
β2-microglobulin	79.8 ± 12.2	72.3 ± 18.2	0.109
κFLC	55.8 ± 13.7	44.6 ± 18.9	0.022
λFLC	56.1 ± 11.4	40.9 ± 9.0	<0.001

Adapted from Lim JH, et al. 2020.

Efficacy : Pre-dialysis plasma concentrations of middle molecules

- MCO군은 HF군 대비하여, 12주 차에 베이스라인과 비교 시 **κFLC 및 λFLC의 투석 전 혈장 농도 수치가 유의하게 감소**하였습니다.[1]

Interval changes in the middle molecules levels[1]



Adapted from Lim JH, et al. 2020.

β2-MG, β2-microglobulin; HF, high-flux; κFLC, kappa free light chain; λFLC, lambda free light chain; MCO, medium cut-off