

Cardiovascular risk in patients undergoing maintenance hemodialysis with Helixone[®] membrane: a multicenter randomized study

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KEY WORDS

cardiovascular risk,
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membrane, high-flux
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ABSTRACT

INTRODUCTION The high prevalence and incidence of atherosclerotic vascular complications, such as cardiovascular disease, remain the major cause of morbidity and mortality in patients undergoing dialysis.

OBJECTIVES The aim of the study was to evaluate cardiovascular risk factors in patients dialyzed with a high-flux polysulfone membrane (Helixone[®]) compared with those dialyzed with a low-flux polysulfone membrane.

PATIENTS AND METHODS This was a crossover randomized study including 90 hemodialysis patients. Group 1 was treated first with high-flux and then with low-flux membranes, while group 2, first with low-flux and then with high-flux membranes for 13 months. Clinical, biochemical, and echocardiographic data were evaluated at baseline and every 3 months during the study.

RESULTS After 6 months of high-flux dialysis, we observed a significant decrease in β_2 -microglobulin, lipoprotein(a), C-reactive protein, and parathormone levels and an increase in serum albumin levels. Initially, both groups showed left ventricular hypertrophy. After 6 months of high-flux dialysis, we observed a tendency for an increase in the cardiac index and cardiac output and a decrease in isovolumic relaxation time.

CONCLUSIONS Our study showed that the use of high-flux dialysis with the Helixone[®] membrane, in comparison with low-flux dialysis with polysulfone membranes, improves middle-molecular clearance. In addition, we showed that a reduction in chronic inflammation during high-flux dialysis may decrease cardiovascular risk. However, further research with longer follow-up is needed to verify our echocardiographic findings.

INTRODUCTION High prevalence and incidence of atherosclerotic vascular complications, such as cardiovascular disease, remain a major cause of morbidity and mortality in dialysis patients. Cardiac causes account for nearly half of all deaths in

this patient group.^{1,2} Several studies have shown that high-flux dialysis provides significant benefits compared with traditional (low-flux) dialysis.^{3,4} The main advantage of high-flux dialysis is the greatest solute fluxes both for low- and

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middle-molecular weight uremic toxins. The use of ultrapure bicarbonate dialysate and downregulation membrane reactivity increase biocompatibility of this type of dialysis. Elderly patients and those at high cardiovascular risk may also benefit from high-flux dialysis through better hemodynamic tolerance and improved cardiovascular stability.⁵⁻⁸

Nanotechnology membrane fabrication procedures provide Helixone®—a high-flux polysulfone membrane—with a highly defined pore structure and distribution at the innermost, separating region of the membrane. The technological advances of the Helixone® membranes are all aimed at improving dialysis treatment and patients' quality of life.⁹⁻¹¹

The aim of the study was to evaluate cardiovascular risk factors in patients undergoing dialysis with a high-flux membrane in comparison with those undergoing dialysis with a standard low-flux polysulfone membrane. Patients were treated with high-flux and low-flux polysulfone membranes for 6 months each, with a 4-week washout period in between.

PATIENTS AND METHODS **Characteristics of the study group**

This was a crossover randomized study in 90 stable patients on hemodialysis (mean age, 52.5 ± 9.8 years) from 6 dialysis centers in Poland. Before enrollment, all patients were dialyzed using polysulfone dialyzers and were randomly assigned either to a low-flux membrane (F8 HPS Fresenius Medical Care, Bad Homburg, Germany) or switched to a high-flux membrane (FX100 Helixone®, Fresenius Medical Care). Group 1 comprised 55 patients who were treated with high-flux dialysis during the first 6 months, and, after a 4-week cross-over washout period, with low-flux dialysis for the next 6 months. Group 2 comprised 35 patients who underwent dialysis first with low-flux membranes, and, after a 4-week crossover washout period, they were switched to high-flux membranes for the next 6 months. The approval of the local ethics committee was obtained, and all patients gave written informed consent to participate in the study.

All except 3 patients had hypertension and received 1 to 4 antihypertensive drugs (renin-angiotensin-aldosterone system antagonists, β -adrenergic blockers, or calcium channel blockers). Seventy patients were taking calcium carbonate at a mean daily dose of 4.2 ± 2.8 g; 11 patients were taking calcium acetate at a mean daily dose of 4.3 ± 2.9 g; and 69 patients were taking alfacacicol at a dose of 0.3 ± 0.13 mg/d. Sevelamer was administered at a mean dose of 1800 mg/d in 8 patients. Diabetes was reported in 15 patients (22.2%), and coronary heart disease in 25 (37.0%). All patients were in a clinically stable condition.

Inclusion and exclusion criteria The inclusion criteria were as follows: age, 18–65 years; duration of hemodialysis, at least 3 months;

hemodialysis before the study using low-flux membranes and stable parameters, at least 1 month; Kt/V ≥ 1.2; a well-functioning fistula natural or polytetrafluoroethylene (minimal blood flow, 300 ml/min); no signs of infection during the month before the study (C-reactive protein [CRP], < 30 mg/l); stable hemoglobin at a range of 11 to 13 g/dl; and adequate iron status according to the European Best Practice Guidelines¹²; and dialysis with ultrapure water.

The exclusion criteria were as follows: uncontrolled hypertension (≥ 160/100 mmHg before dialysis); need for hospitalization; active malignancy; serious heart, lung, or liver disease; concentration of plasma albumin, < 3.0 g/dl; lack of informed consent; estimated survival of less than 12 months; and participation in another clinical study.

Characteristics of dialysis treatment Dialysis conditions remained stable during the study, and all patients were dialyzed 3 times a week. Blood and dialysate flow rates, membrane surface area, duration of a dialysis session, urea reduction ratio (Kt/V), and dialysate quality remained unchanged throughout the study. The mean time of a dialysis session was 4 to 4.5 hours, and ultrafiltration was about 2000 to 3000 ml. The blood flow rate ranged from 287 to 300 ml/min, and the arterial and venous blood pressure were in normal ranges.

The characteristics of the high-flux membrane were as follows: surface area, 2.2 m²; sieving coefficient (Q_b = 300 ml; Q_F = 60 ml/min) for β_2 -microglobulin, 0.8. The characteristics of the low-flux membrane were as follows: surface area, 1.8 m²; no data were available for the β_2 -microglobulin reduction rate.

Clinical and biochemical data Clinical data as well as dialysis prescription and its adequacy were evaluated before the study, and every 3 months during the study. The clinical data included incidents (number) of blood transfusions, intradialytic hypotension, acute coronary events and arrhythmias, transient ischemic attacks, vascular ischemic events, hospitalization, and deaths.

Data on the mean arterial pressure, heart rate, Kt/V, and interdialysis weight gain were collected during follow-up. Routine biochemical measurements (CRP, albumin, iron status, calcium, phosphorus, parathormone, lipid profile, and complete blood count) as well as measurement of β_2 -microglobulin, lipoprotein(a), and homocysteine levels were performed at baseline and every 3 months. Serum β_2 -microglobulin concentrations and lipoprotein(a) were measured by nephelometry using immunonephelometrical kits (Dade Behring GmbH, Marburg, Germany). The plasma concentration of homocysteine was measured by an enzyme-linked immunosorbent assay (IBL International GmbH, Hamburg, Germany). Blood samples were collected after overnight fasting before midweek hemodialysis sessions.

TABLE 1 Changes of biochemical parameters during 6 months of dialysis

Parameters	At baseline	At 3 months	At 6 months	P value
group 1 (high-flux followed by low-flux)				
C-reactive protein, mg/l	9.3 ± 19.5	9.1 ± 19.3	6.0 ± 6.9	0.05
albumin, g/l	38.4 ± 10.2	39.7 ± 6.4	38.7 ± 7.3	0.98
lipoprotein(a), mg/dl	1.0 ± 5.7	0.2 ± 0.1	0.1 ± 0.3	0.01
β ₂ -microglobulin, mg/l	34.7 ± 14.0	29.3 ± 9.7	30.6 ± 13.4	0.07
parathormone, pg/ml	437.6 ± 419.2	472.7 ± 402.9	439.3 ± 452.4	0.75
group 2 (low-flux followed by high-flux)				
C-reactive protein, mg/l	12.2 ± 27.8	8.8 ± 16.5	6.5 ± 9.2	0.08
albumin, g/l	40.0 ± 6.9	40.9 ± 2.9	41.1 ± 8.6	0.67
lipoprotein(a), mg/dl	0.1 ± 0.2	0.1 ± 0.1	0.1 ± 0.1	0.98
β ₂ -microglobulin, mg/l	40.8 ± 14	28.9 ± 11.2	34.8 ± 12.5	0.01
parathormone, pg/ml	435.7 ± 485.7	499.4 ± 470.9	535.3 ± 501.3	0.08
groups 1 (high-flux followed by low-flux) + group 2 (low-flux followed by high-flux)				
C-reactive protein, mg/l	9.1 ± 18.4	8.2 ± 16.5	3.9 ± 6	0.01
albumin, g/l	39.4 ± 8.6	40.3 ± 7.4	43.8 ± 19.6	0.05
lipoprotein(a), mg/dl	0.7 ± 4.7	0.2 ± 0.2	0.1 ± 0.2	0.05
β ₂ -microglobulin, mg/l	33.5 ± 13.6	31.8 ± 11.3	23.0 ± 21.7	0.01
parathormone, pg/ml	457.9 ± 434.8	503.5 ± 451.2	266.7 ± 412.2	0.05

Data are expressed as mean ± standard deviation.

The adequacy of dialysis treatment was estimated by Kt/V.

Echocardiography Echocardiography (Phillips HP 11XE with a 2–3 MHz transducer) was performed at baseline and every 6 months before the mid-week dialysis session by 2 independent investigators. The mean value was calculated from 5 consecutive cyclical measurements. In parasternal long- and short-axis views, systolic and diastolic left ventricular dimensions, interventricular septum thickness, and posterior wall thickness were measured together with aortic annulus, left atrium, and right ventricular diameters. Cardiac output was calculated by multiplying the aortic area and aortic flow interval and heart rate. The cardiac index was calculated by dividing the cardiac output by the body surface area. Pulsed Doppler measurements of the left ventricular mitral inflow from the 4-chamber apical view, where sample volume was placed at the level of valve tips, included mitral early peak velocity of early and atrial waves. The ratio of early to atrial velocity was calculated. Isovolumic relaxation time (IVRT) was measured as the time between aortic valve closure and mitral valve opening. The echocardiographic assessment of pulmonary artery pressure (PAP) was performed by measuring tricuspid regurgitant jet velocity (TR) and adding estimated right atrial pressure, depending on the inferior vena cava diameter. The obtained parameters were used to calculate PAP using the modified Bernoulli equation: $PAP = 4V2TR + RAP$ (mmHg).

Statistical analysis Data were expressed as means ± standard deviation. Statistical significance was set at a P value of 0.05 or lower. Differences

among the groups were analyzed with the t test and Mann–Whitney test. The χ^2 test was used for categorical variables. The Friedman's analysis of variance was used to assess the significance of longitudinal changes. All statistical analyses were performed with the Statistica 7.1 software (Kraków, Poland).

RESULTS Low serum albumin levels (<38 g/l) were observed in 11.1% of the patients, while elevated CRP levels (>10 but <30 mg/l) in 23.3%. Two patients died during the study. The adequacy of dialysis was stable during follow-up. There were no differences between groups 1 and 2 with respect to clinical data. Most of the biochemical parameters were stable during the 12-month follow-up in both groups. In group 1, β₂-microglobulin and lipoprotein(a) levels decreased significantly after the first 3 months of high-flux dialysis (34.7 vs. 29.3 mg/l; 1.0 vs. 0.2 mg/dl, respectively). Moreover lipoprotein(a) levels decreased significantly after 6 months (0.2 vs. 0.1 mg/dl), while albumin concentrations significantly increased after 9 months (38.4 vs. 40.2 g/l). In group 2, a significant decrease in β₂-microglobulin levels was observed after switching from low-flux to high-flux membranes (40.8 vs. 34.8 mg/l; $P = 0.01$) (TABLE 1).

To obtain more powerful statistical data, calculations were made in the whole study population (n = 90). After 6 months of high-flux dialysis in each group, we observed a significant decrease in β₂-microglobulin, lipoprotein(a), CRP, and parathormone levels, and a significant increase in serum albumin levels. A tendency for a decrease in homocysteine levels after 6 months of high-flux dialysis was also observed.

TABLE 2 Echocardiographic parameters before and after 6 months of high-flux dialysis

Parameters	Before dialysis	After dialysis	<i>P</i> value
LVEDd, mm	48.4 ± 8.3	48.2 ± 7.7	0.8
LVESd, mm	32.2 ± 7.7	32.5 ± 7.8	0.8
HR, bpm	78.3 ± 10.7	79.5 ± 8.6	0.9
IVRT, ms	102.2 ± 38.0	100.5 ± 21.5	0.4
IVC, mm	12.5 ± 2.0	14.6 ± 4.8	0.2
E/A	1.0 ± 0.4	1.0 ± 0.4	0.8
IVDd, mm	13.0 ± 1.9	12.6 ± 1.9	0.6
IVSd, mm	15.4 ± 3.0	16.6 ± 1.8	0.1
LAd, mm	39.1 ± 6	38.6 ± 7.1	0.2
CI, l/min/m ²	4.2 ± 1.1	4.9 ± 2.2	0.2
CO, l/min	7.9 ± 2.4	9.0 ± 4.3	0.2
PAP, mmHg	25.5 ± 9.4	25.9 ± 9.0	0.8
RV, mm	26.7 ± 4.2	27.0 ± 5.0	0.6
PWd, mm	10.6 ± 1.6	10.6 ± 1.9	0.6
PWSd, mm	13.9 ± 3.5	16.6 ± 1.4	0.5

The data were expressed as mean ± standard deviation.

Abbreviations: Ao – aortic ring diameter, CI – cardiac index, CO – cardiac output, E/A – early to atrial mitral inflow velocity ratio, HR – heart rate, IVC – inferior vena cava, IVDd – interventricular septum diastolic diameter, IVSd – interventricular septum systolic diameter, IVRT – isovolumic relaxation time, LAd – left atrial diameter, LVEDd – left ventricular end-diastolic diameter, LVESd – left ventricular end-systolic diameter, PAP – pulmonary artery pressure, PWd – posterior wall diastolic diameter, PWSd – posterior wall systolic diameter, RV – right ventricle

In both groups, left ventricular hypertrophy was observed. After 6 months of high-flux dialysis, a nonsignificant tendency for an increase in the cardiac index and cardiac output as well as a decrease in IVRT were observed in both groups (TABLE 2).

DISCUSSION The European Best Practice Guidelines³ recommend the use of high-flux membranes to delay long-term complications of hemodialysis therapy. Use of these membranes reduces the risk of dialysis-related amyloidosis, improves calcium and phosphate balance, reduces the use of erythropoiesis-stimulating agents and the need for anemia treatment, and reduces cardiovascular risk.^{13,14} However, the Haemodialysis (HEMO) Study (HEMO)¹⁵ showed no difference in survival between patients treated with low-flux dialysis and those treated with high-flux dialysis. Nevertheless, the subgroup analysis in the HEMO study suggested that the use of high-flux membranes decreased the risk of death from cardiovascular causes. Moreover, it showed that mortality was inversely correlated with the β_2 -microglobulin concentration, especially if associated with inflammation.^{16,17} Also, the Membrane Permeability Outcome (MPO) Study,¹⁸ which examined the survival of 647 patients depending on dialysis modality (high-flux vs. low-flux), showed that there was no difference between the 2 studied groups. However, a further analysis of the MPO study showed a decreased risk of death in patients with a serum albumin level of 40 g/l or higher and in patients

with diabetes treated with high-flux dialysis in comparison with patients with diabetes or low albumin levels treated with low-flux dialysis.¹⁹

In our study, we compared the effects of a high-flux membrane (Helixone®) with those of a standard polysulfone membrane on β_2 -microglobulin removal, levels of lipoprotein(a) and inflammatory markers, and clinical outcome. During 6 months of using high-flux membranes, we observed a significant decrease of β_2 -microglobulin, lipoprotein(a), and CRP levels and a nonsignificant decrease of cardiovascular risk factors such as parathormone and homocysteine, which is in line with the available data.^{7,20–22} The elevated levels of β_2 -microglobulin and lipoprotein(a) and acute-phase response activation may contribute to excessive cardiovascular mortality related to atherosclerosis in patients on maintenance hemodialysis.²³

A decrease in β_2 -microglobulin levels during high-flux dialysis has been reported before.^{24,9,22} In our study, the Helixone® membrane, similarly to other high-flux membranes, was more effective in β_2 -microglobulin removal compared with low-flux membranes. However, Mandolfo et al.²⁴ reported that the rate of reduction in β_2 -microglobulin levels was related to a larger dialyzer surface. A larger surface area could also be responsible for a more efficient β_2 -microglobulin removal in patients dialyzed with the Helixone membrane, which had a surface of 2.2 m² compared with a surface of 1.8 m² for the low-flux membrane. However, a significant decrease in lipoprotein(a) and CRP levels and an increase in the albumin concentration may be related to other features of the Helixone membrane than the surface area.^{9–11}

A clinically important finding of our study was a reduction in serum CRP concentrations. An association between inflammatory cytokines and dialysis modality was suggested by other authors.²⁵ An inflammatory process (increased levels of interleukin 6 and CRP) has been reported in hemodialysis patients. It may have several potential causes including bacterial contamination of the dialyzer, dialyzing membrane incompatibility, and vascular access.^{26,27} Our results suggest that a long-term use of Helixone® membranes is associated with a decrease in CRP levels. However, the effect of other factors such as the time on maintenance dialysis or simultaneous pharmacological treatment cannot be excluded. However, we may assume that the decrease was caused by the use of biocompatible membranes.

A unique manufacturing technology provides the Helixone® membrane with a highly defined pore structure and distribution at the innermost, separating region of the membrane. This technological advancement is aimed at improving the therapy, mostly by ensuring biocompatibility and thereby reducing inflammation in patients on maintenance hemodialysis. Other authors reported that the Helixone® membrane has high hemocompatibility and endotoxin retention capacity.¹⁰

Wanner et al.³ reported a significant decrease in oxidized low-density lipoprotein levels and a significant improvement in lipid and apolipoprotein profiles in patients treated with a Helixone membrane.

In our study, the main abnormality on echocardiographic examination was cardiac asymmetric hypertrophy of the left ventricle. The parameters of the left and right ventricles and the inferior vena cava were stable during the study. A non-significant but clinically important increase in the cardiac output and cardiac index as well as a tendency for a decrease in prolonged IVRT in patients on high-flux treatment were observed, suggesting that high-flux dialysis with the Helixone® membrane could improve cardiac systolic and diastolic function in dialysis patients. The values of the cardiac output and cardiac index with a stable aortic root diameter and heart rate increased only because of higher aortic flow velocity, which suggests an improvement in systolic left ventricular function. A negative correlation between the degree of renal dysfunction and impaired left ventricular relaxation has been well-documented—the lower the glomerular filtration rate, the longer the IVRT.²⁸ The normal IVRT value in the fourth and fifth decades of life is 79 ±11 ms. In our study, IVRT was prolonged (the mean value was 102 ±38 ms).^{29,30} We believe that advances in the treatment with high-flux membranes might result in improvement of the left ventricular diastolic function and reduction in IVRT.

In conclusion, our study showed that dialysis with the Helixone® membrane, but not with a low-flux polysulfone membrane, improves middle-molecular clearance. In addition, we showed that a reduction in chronic inflammation during dialysis with a high-flux membrane may decrease cardiovascular risk. However, further research with longer follow-up is needed to verify our echocardiographic findings and to assess the effect of the Helixone® membrane on cardiovascular risk factors.

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Ryzyko sercowo-naczyniowe u pacjentów hemodializowanych z użyciem błony typu Helixone®: randomizowane badanie wieloośrodkowe

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SŁOWA KLUCZOWE

błona dializacyjna
typu Helixone®, dializa
high-flux, ryzyko
sercowo-naczyniowe

STRESZCZENIE

WPROWADZENIE Duża częstość występowania powikłań naczyniowych związanych z miażdżycą, takich jak choroby układu krążenia, pozostaje główną przyczyną chorobowości i śmiertelności u pacjentów dializowanych.

CELE Celem badania była ocena czynników ryzyka sercowo-naczyniowego pacjentów dializowanych za pomocą błony polisulfonowej *high-flux* typu Helixone® w porównaniu do pacjentów dializowanych za pomocą błony polisulfonowej *low-flux*.

PACJENCI I METODY W badaniu wzięło udział 90 pacjentów hemodializowanych. W grupie 1 najpierw zastosowano błony *high-flux*, a następnie błony *low-flux*, a w grupie 2 najpierw błony *low-flux*, a następnie *high-flux* przez 13 miesięcy. Dane kliniczne, biochemiczne oraz echokardiograficzne oceniano przed rozpoczęciem badania, a następnie co 3 miesiące w trakcie badania.

WYNIKI Po 6 miesiącach dializy *high-flux* zaobserwowano istotny spadek stężenia β_2 -mikroglobuliny, lipoproteiny (a), białka C-reaktywnego, parathormonu oraz wzrost stężenia albuminy. Początkowo w obu badanych grupach stwierdzono przerost lewej komory. Po 6 miesiącach dializy *high-flux* zaobserwowano tendencję do zwiększenia się wskaźnika sercowego i pojemności minutowej serca oraz spadek czasu izowolumetrycznej relaksacji.

WNIOSKI Nasze badanie wykazało, że dializa *high-flux* z użyciem błony typu Helixone® poprawia klirens średnich cząsteczek w porównaniu do dializy *low-flux* z błonami polisulfonowymi. Ponadto wykazaliśmy, że zmniejszenie przewlekłego stanu zapalnego podczas dializy *high-flux* może zmniejszać ryzyko sercowo-naczyniowe u pacjentów. Konieczne są jednak dalsze badania z dłuższym okresem obserwacji w celu zweryfikowania zmian obserwowanych w badaniu echokardiograficznym.

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