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Use of medium cut-off membrane dialyzer compared to high flux membrane dialyzer in improving the clearance of middle to large molecule uremic toxins: A Systematic Review

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Abstract

Background: The loss of kidney function in patients with kidney disease leads to the accumulation of dissolved substances known as uremic toxins, which can negatively impact patient health. Membranes with a high number of pores, such as those in high-flux dialyzers, allow some medium-sized molecules like beta-2 microglobulin to pass through. However, these membranes are less effective at filtering out larger dissolved substances. Larger medium-sized molecules (>25 kD) need to be removed either by convection or through the use of highly permeable membranes such as Medium Cut-Off (MCO) membranes. Therefore, it is important to understand the improvement in uremic toxin clearance when using MCO dialyzers compared to high-flux dialyzers.

Purpose: To evaluate and compare the effectiveness of using medium cut-off (MCO) membrane dialyzer with high flux membrane dialyzer.

Method: A systematic review with article selection guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The systematic review process begins with the formulation of clinical questions relevant to the topic. Before this, the authors establish PICOS criteria, which stand for: P (problem, patient, or population), I (intervention, prognostic factor, or exposure), C (comparison or control), O (outcome), and S (study design). For this article, P: Patients with chronic kidney disease undergoing hemodialysis, I: Use of dialyzers with medium cut-off (MCO) membrane, C: Use of dialyzer with high flux membrane, O: Increased clearance of uremic toxins of middle to large molecules, such as β 2-microglobulin, kappa and lambda free light chains, S: Randomized controlled trials. The article search was conducted systematically using the keywords: "Medium cut-off dialyzer" AND "High flux dialyzer" AND "Uremic toxins" AND "Middle molecules" AND "Large molecules" AND "Clearance Hemodialysis".

Results: The use of MCO membranes was more effective in eliminating medium-to-large uremic toxins while maintaining safety and regulation comparable to conventional hemodialysis with high-flux dialyzers. MCO membranes were also more effective even with low blood flow, without significantly increasing albumin loss. Additionally, MCO membranes contributed to reducing inflammation and allowed for shorter recovery times post-hemodialysis treatment.

Conclusion: Given its comparable safety to high-flux dialyzers, the use of MCO membranes can be expanded in clinical practice at hemodialysis centers, including those in resource-limited settings.

Keywords: High Flux; Large Middle Molecules; Medium Cut-Off Membrane; Uremic Toxins.

INTRODUCTION

The loss of kidney function in patients with kidney disease leads to the accumulation of dissolved substances known as uremic toxins, which can negatively affect patients' health. The uremic syndrome is caused by the progressive retention of a large number of compounds that are normally excreted by healthy kidneys. These compounds are referred to as uremic retention solutes or uremic toxins when they interact negatively with biological functions (Boschetti, Voigt, Storr, & Krause, 2013).

These toxins can be categorized into small molecules (water-soluble), middle molecules, and protein-bound solutes. While small molecules with a molecular weight of up to 0.5 kDa can be effectively removed by dialysis, conventional dialysis has limitations in clearing middle molecules ranging from 0.5 to 60 kDa. Middle molecules can be further divided into two groups based on their molecular weight: conventional middle molecules (0.5–25 kDa) and larger middle molecules (>25 kDa) (Boschetti, Voigt, Storr, & Krause, 2015). The first group includes β 2-microglobulin (11.8 kDa), which has historically been regarded as the standard representative of middle molecules, while the latter includes immunoglobulin free light chains such as lambda free light chains (45 kDa). These larger middle molecules are associated with inflammation, cardiovascular events, and other comorbidities in dialysis patients, including cardiovascular disease, mineral and bone disorders, and infections (Zhou, Chen, & Wang, 2017).

Hemodialysis (HD) is the most commonly performed dialysis procedure worldwide, aiming to remove solutes, including small molecules (<0.5 kDa) and conventional middle molecules (0.5–25 kDa), primarily through diffusion and with very limited convection. Membranes with high pore density, such as those found in high-flux dialyzers, allow some middle molecules like β 2-microglobulin to pass through, but these membranes are less effective at filtering larger solutes. Larger middle molecules (>25 kDa) require removal either through convection or by using highly permeable membranes (Kandi, Brignardello, Couban, Wu, & Nesrallah, 2022).

To improve the clearance of middle-sized molecules, highly permeable High Cut-Off (HCO) dialyzers have been developed. Previous clinical trials have shown that HCO membranes reduce certain

immune mediators in plasma (e.g., sTNFR1) when used and affect vascular calcification in in vitro results. However, routine treatment of chronic dialysis patients with HCO membranes cannot be continued due to significant albumin loss. Recently, a new type of membrane with a lower and more gradual cut-off, known as the medium cut-off (MCO) membrane, has been developed. The adjusted pore size of the MCO membrane promotes the removal of large toxins while ensuring albumin retention (Eiamcharoenying, Takkavatakam, Chariyavilaskul, Susantitaphong, Eiam, & Tiranathanagul, 2022).

The use of Medium Cut-Off (MCO) dialyzers can also be defined as Expanded Hemodialysis (HDx). Expanded Hemodialysis (HDx) is a dialysis treatment that combines diffusion and convection along the hollow fiber of the dialyzer equipped with a membrane that has high initial retention capacity. In its application, HDx does not require specific hardware modifications, substitution fluid preparation, or additional nursing skills when compared to conventional hemodialysis (HD) in standard mode (Fiorentino, La Fergola, & De Rosa, 2024).

RESEARCH METHOD

A systematic review with article selection guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The systematic review process begins with the formulation of clinical questions relevant to the topic. Before this, the authors establish PICOS criteria, which stand for: P (problem, patient, or population), I (intervention, prognostic factor, or exposure), C (comparison or control), O (outcome), and S (study design). For this article, P: Patients with chronic kidney disease undergoing hemodialysis, I: Use of dialyzers with medium cut-off (MCO) membrane, C: Use of dialyzer with high flux membrane, O: Increased clearance of uremic toxins of middle to large molecules, such as β 2-microglobulin, kappa and lambda free light chains, S: Randomized controlled trials.

The article search was conducted systematically using the keywords: "Medium cut-off dialyzer" AND "High flux dialyzer" AND "Uremic toxins" AND "Middle molecules" AND "Large molecules" AND "Clearance Hemodialysis". The inclusion criteria inquired the

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selected articles were in the form of Randomized Controlled Trials, Cohort Studies, and Observational Studies published between 2017-2024, only full-text articles written in English were included, article in the form of literature reviews, scoping reviews, and meta-analyses were also included. The exclusion criteria included Studies that did not report results related to uremic toxin clearance, articles that are not available in full-text.

The initial search resulted in 59 article from Scienedirect, 71 from Pubmed, 55 from Coachrane Library, 13 from Proquest and 19 from Sage Journal. After screening and filtering based on the predefined criteria, 7 articles met the inclusion criteria and were selected for further analysis.

RESEARCH RESULTS

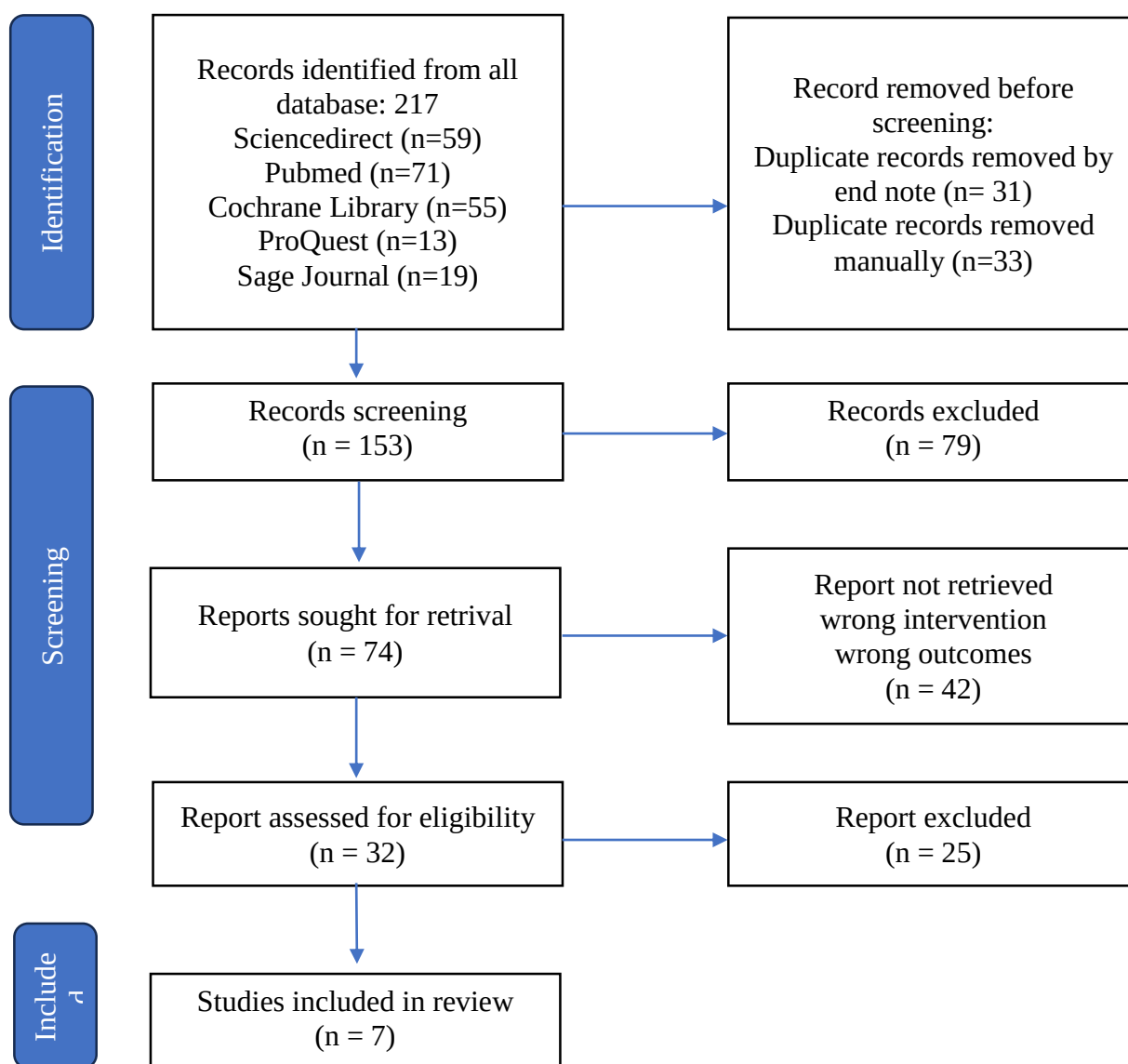


Figure 1. PRISMA Flow Diagram

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Table The Main Characteristics of Included Studies

(Author, Year) (Country)	Purpose	Method	Results
(Weiner et al., 2020) (USA)	This randomized trial evaluated the efficacy and safety of hemodialysis treatment with a medium cut-off dialyzer.	Clinically stable patients on maintenance hemodialysis were randomized to receive dialysis with either a medium cut-off dialyzer (Theranova 400) or a high-flux dialyzer (Elisio-17H) over 24 weeks of treatment. The primary safety end point was the predialysis serum albumin level after 24 weeks of treatment. The primary efficacy end point was the reduction ratio of free λ light chains at 24 weeks of treatment.	Hemodialysis therapy with the Theranova 400 dialyzer provides superior removal of larger middle molecules, as exemplified by free λ light chains, compared with a similar size high-flux dialyzer, while maintaining serum albumin level.
(Belmouaz et al., 2020) (France)	Assess how well each dialyzer removes uremic toxins such as β_2 -microglobulin, myoglobin, and light chains.	This cross-over prospective study included 40 patients randomly assigned to receive either 3 months of MCOHD followed by 3 months of high-flux HD (HF-HD), or vice versa. The primary endpoint was myoglobin reduction ratio (RR) after 3 months of MCO-HD. Secondary endpoints were the effect of MCO-HD on other middle-weight toxins and protein-bound toxins, and on parameters of nutrition, inflammation, anaemia and oxidative stress.	Compared with HF-HD, MCO-HD provides higher myoglobin and other middle molecules RR and is associated with moderate hypoalbuminemia. The potential benefits of this strategy on long-term clinical outcomes deserve further evaluation.
(Sevinc et al., 2020) (Turkey)	To compare medium cut-off and high-flux dialyzers as regards their intra- and interdialysis effect on circulating levels of middle and large uremic toxins and serum albumin	Fifty-two patients were randomized to have hemodialysis with either 3 months of high-flux dialyzer followed by 3 months of MCO or vice versa. Blood samples were taken before and after dialysis at the first and last sessions of each dialyzer for analyses of middle and large uremic toxins including inflammatory mediators and vascular endothelial growth factor (VEGF), and serum albumin.	The decline in circulating levels of several middle and large uremic toxins including VEGF following hemodialysis was more pronounced when using MCO membranes as compared to high-flux membranes while their effect on inflammatory molecules was similar.

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(Author, Year) (Country)	Purpose	Method	Results
(Zickler et al., 2017) (Germany)	Assess whether MCO dialyzer can reduce biomarkers of inflammation such as IL-6, CRP, and TNF- α .	The randomized crossover trial in 48 patients compared MCO-Ci dialysis to High-flux dialysis of 4 weeks duration each plus 8 weeks extension phase. Primary endpoint was the gene expression of TNF- α and IL-6 in peripheral blood mononuclear cells (PBMCs), secondary endpoints were plasma levels of specified inflammatory mediators and cytokines.	MCO-Ci dialyzers modulate inflammation in chronic HD patients to a greater extent compared to High-flux dialyzers. Transcription of pro-inflammatory cytokines in peripheral leukocytes is markedly reduced and removal of soluble mediators is enhanced with MCO dialysis. Serum albumin concentrations stabilize after an initial drop. These results encourage further trials with longer treatment periods and clinical endpoints.
(Bolton et al., 2021) (Ukraina)	Evaluate the impact of changing hemodialysis therapy mode on post-dialysis recovery time and symptom burden felt by patients.	A dialysis unit decided to perform regular assessments of patient-reported symptom burden, using the POS-S Renal Symptom questionnaire and the "Recovery time from last dialysis session" question as part of routine patient focused care. At a similar time, a clinical evidence-based decision was taken to switch the in-center dialysis cohort from regular high-flux dialysis membrane to medium cut-off (MCO) membrane, introducing HDx therapy.	Regular assessment of patient reported symptoms is feasible in routine dialysis practice and can help in evaluating the impact of clinical interventions. Observations suggest that HDx therapy may reduce post-dialysis recovery time and improve perceived fatigue level.
(Garcia et al., 2018) (Spain)	The aim of this study is to evaluate the efficacy of an MCO dialyser in the removal of small and medium-size molecules and compare it with standard high-flux (HF) dialysers in HD and OL-HDF.	In this crossover study, 18 prevalent HD patients were studied in three single mid-week dialysis treatments during three consecutive weeks as follows: first week with OL-HDF with a standard HF dialyser, second week with conventional HD with a standard HF dialyser and third week with conventional HD with an MCO dialyser. Reduction ratios (RRs) of different-sized molecules and albumin losses were collected for the different dialysers.	MCO HD is superior to standard HF HD in the removal of middle and larger middle molecules and it is not inferior to OL-HDF in the clearance of small and larger middle molecules. Thus it could be an alternative in patients in which it is not possible to perform OL-HDF.

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(Author, Year) (Country)	Purpose	Method	Results
(Kim et al., 2020) (Korea)	This study evaluated the efficacy of a medium cut-off (MCO) dialyser in removing large middle molecular uremic toxins and compared it with that of conventional high-flux (HF) dialysers in HD and predilution OL-HDF.	Six clinically stable HD patients without residual renal function were investigated. Dialyser and treatment efficacies were examined during a single midweek treatment in three consecutive periods: 1) conventional HD using an HF dialyser, 2) OL-HDF using the same HF dialyser, and 3) conventional HD using an MCO dialyser. Treatment efficacy was assessed by calculating the reduction ratio (RR) for β 2-microglobulin (β 2M), myoglobin, κ and λ free light chains (FLCs), and fibroblast growth factor (FGF)-23 and measuring clearance for FLCs.	MCO HD showed significantly greater RR of large middle molecules and achieved improved clearance for FLCs than conventional HD and OL-HDF, without the need for large convection volumes or high blood flow rates. This would pose as an advantage for elderly HD patients with poor vascular access and HD patients without access to OL-HDF.

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DISCUSSION

Demonstrated that the use of medium cut-off (MCO) dialyzers—particularly Theranova 400—consistently provides superior efficacy in removing middle- to large-sized molecules such as β 2-microglobulin, prolactin, and λ -free light chains compared to high-flux (HF) dialyzers in the context of conventional hemodialysis (HD). MCO performance in HD was shown to match or even exceed the efficacy of online hemodiafiltration (OL-HDF) using HF dialyzers (Wolley, Jardine, & Hutchinson, 2018).

The use of MCO dialyzers presents a practical and accessible option for enhancing dialysis quality in standard hemodialysis settings, especially in low-resource or rural healthcare facilities where online hemodiafiltration (OL-HDF) is unavailable. Several studies have demonstrated that MCO membranes provide improved removal of larger uremic toxins, such as β 2-microglobulin and free light chains, without the need for complex infrastructure or substitution fluid. This capability not only helps reduce the burden of dialysis-related complications, such as chronic inflammation and amyloidosis, but also potentially improves patient outcomes and quality of life. Therefore, integrating MCO membranes into routine hemodialysis may represent a cost-effective strategy to bridge the gap in care where advanced modalities like OL-HDF are not feasible (Yang, Ke, Liao, Guo, & Gao, 2022).

Transitioning from conventional HD to more intensive home hemodialysis (IHD) led to clinically meaningful reductions in post-dialysis recovery time (DRT) and improvements in symptom burden, including fatigue, muscle cramps, and sleep disturbances. Although the type of dialyzer was not specifically addressed, the combination of higher dialysis intensity and increased frequency appears to play a key role in enhancing patient quality of life (Mjoen, Reisaeter, Hallan, Line, Hartmann, Midtvedt, & Holdass, 2016).

Integrating more selective dialyzer types (such as MCO membranes) with adjusted therapy modalities (e.g., home-based IHD) may offer a more holistic approach to managing dialysis patients. Efficient toxin clearance alone is insufficient without considering patient comfort and recovery. These three studies synergistically highlight that improvements in dialysis quality rely not only on filtration technology but also on

how therapy is implemented in clinical practice (Yamamoto, Kazama, Wakamatsu, Takahashi, Kaneko, Goto, & Narita, 2016).

Such trials would provide more robust evidence regarding the clinical advantages of MCO membranes beyond toxin clearance, particularly in improving patient-centered outcomes. Understanding whether the enhanced removal of middle to large molecular weight uremic toxins translates into reduced hospitalization rates, better quality of life, and improved cardiovascular health remains a critical area of investigation. Moreover, assessing the safety profile of MCO membranes over longer treatment periods will help determine their sustainability as a standard dialysis modality. Integrating patient-reported outcomes and cost-effectiveness analyses will also be crucial in shaping future dialysis guidelines and clinical decision-making (Santos, Chen, Casey, Womer, & Wen, 2018).

These results suggest that MCO dialyzers, such as Theranova, offer a promising alternative for patients with hemodynamic instability or limited vascular access, where achieving high blood flow rates may not be feasible. The ability of MCO membranes to effectively clear middle to large molecule uremic toxins without compromising albumin levels highlights their clinical advantage over conventional high flux dialyzers. The maintained safety profile observed across studies reinforces the feasibility of integrating MCO dialyzers into routine hemodialysis practice, particularly for patients at higher risk of toxin accumulation. This underscores the potential of MCO technology to improve dialysis efficacy while ensuring patient safety (Nicholas, Alicic, & Shen, 2022).

The enhanced permeability of MCO membranes enables more efficient clearance of a broader range of middle to large uremic toxins, including larger molecules such as free light chains, without significant loss of essential proteins like albumin. This improved toxin removal is associated with better clinical outcomes, such as reduced inflammation, improved nutritional status, and potentially decreased dialysis-related complications. The use of MCO dialyzers presents a promising advancement in hemodialysis technology, offering a safer and more effective alternative to conventional high flux membranes,

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particularly for patients with elevated levels of larger uremic toxins that are inadequately cleared by standard dialysis (Van Perre, Jones, & Jayne, 2021).

Their research not only confirmed the effectiveness of medium cut-off (MCO) membranes in removing middle to large molecular weight uremic toxins, but also demonstrated their safety profile. The studies showed no increased risk of adverse effects or dialyzer-related reactions, indicating that MCO dialyzers are both efficient and well-tolerated in clinical settings. These findings support the broader clinical application of MCO membranes as a promising alternative to high-flux dialyzers, especially in enhancing toxin clearance without compromising patient safety (Cobob, & Lindholm, 2017).

Based on the findings, medium cut-off (MCO) dialyzers, particularly the TheraNova 400, represent a significant advancement in modern hemodialysis therapy. These dialyzers offer superior clearance of middle molecules, which are often inadequately addressed by high-flux dialyzers, making them especially beneficial for patients dealing with chronic inflammation or the accumulation of these molecules. Remarkably, these benefits are achieved without increasing the risk of adverse effects, providing a safer option for patients. MCO dialyzers are versatile, effective not only in standard clinical settings but also in more challenging conditions, such as those with low blood flow, thus broadening their applicability in diverse hemodialysis scenarios (Aleksova, Milat, Kotowicz, Pasco, Schultz, Wong & Elder, 2021).

CONCLUSION

Given its comparable safety to high-flux dialyzers, the use of Medium Cut-Off (MCO) membranes presents a promising option for enhancing the clearance of middle to large molecule uremic toxins in hemodialysis patients. The ability of MCO membranes to efficiently remove these toxins, combined with their safety profile, makes them a viable alternative for improving patient outcomes. This potential for improved toxin removal can be especially valuable in resource-limited settings, where access to high-flux dialyzers may be restricted.

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