ORIGINAL ARTICLE

Lipid-Lowering Efficacy and Safety of Fenofibrate and Gemfibrozil in Patients Undergoing Dialysis: A Retrospective Cohort Analysis

Sathit Kurathong, MD[1], Viroonrat Trapcharoen, MD[1], Solos Jaturapisanukul, MD[1], Tanun Ngamvichukorn, MD[1], Wanjak Pongsittisak, MD[1], Thananda Trakarnvanich, MD[1]

[1] Renal Division, Department of Internal Medicine. Faculty of Medicine Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand

Objective: Current clinical guidelines advocate the use of statins for the management of dyslipidemia in patients with chronic kidney disease (CKD) who are not yet on dialysis, but not those on dialysis, leading to uncertainty regarding optimal lipid-lowering strategies in this population. Recently, fibrates have emerged as a therapeutic option for patients with advanced CKD. However, their safety and efficacy in patients undergoing dialysis remain controversial. Therefore, the present study aimed to evaluate the lipid-lowering effects and safety of fenofibrate and gemfibrozil in patients with CKD undergoing dialysis.

Materials and Methods: This was a retrospective study including patients with CKD undergoing dialysis who received fenofibrate or gemfibrozil between January 2012 and December 2018. Patients receiving concomitant lipid-modifying therapy and those with unstable clinical conditions were excluded from the study. Lipid levels were assessed before and 6 to 12 months after fibrate therapy.

Results: A total of 84 patients undergoing dialysis who received fibric acid derivatives (gemfibrozil, n=58; fenofibrate, n=26) were included in the present study. Both fenofibrate and gemfibrozil effectively reduced triglyceride levels. The gemfibrozil group showed a 37% reduction, whereas the fenofibrate group showed a 28% reduction, without a statistically significant difference between the groups (p=0.24). Cholesterol reduction was modest in both groups, without a statistically significant difference between the two groups. No severe adverse effects were reported. Muscle pain was the most prevalent side effect. However, it did not lead to substantial discontinuation rates.

Conclusion: Fibrate therapy, particularly low-dose fenofibrate, is effective and safe for managing dyslipidemia in patients with CKD undergoing dialysis and offers a potential alternative to statins, which have minimal benefits for this population. Further prospective studies are needed to confirm these findings and refine treatment guidelines for dyslipidemia in patients with end-stage kidney disease.

Keywords: Chronic kidney disease; Fenofibrate; Gemfibrozil; Dialysis

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Cardiovascular disease is the leading cause of death in patients with end-stage kidney disease (ESKD). Dyslipidemia is a significant, controllable risk factor for cardiovascular disease. In patients undergoing dialysis, managing lipid disorders becomes even more crucial due to their heightened cardiovascular risk and distinct lipid profile alterations. Physiological changes in various lipid types in patients with chronic kidney disease (CKD) undergoing dialysis differ from those in the general population, depending on comorbid conditions and the type of dialysis received. Typically, these patients exhibit elevated cholesterol levels along with high triglyceride levels, which is known as mixed dyslipidemia.

Current guidelines recommend the use of low-density lipoprotein cholesterol as the primary target for managing dyslipidemia in patients with CKD based on cardiovascular risk. Triglycerides are not recommended as treatment targets. According to the 2019 ESC guidelines, statins or statins combined with ezetimibe for lipid management are the first-line treatment for patients with CKD who are not yet on dialysis. However, starting statins in patients undergoing dialysis is not recommended[1,2]. Previous studies have shown that statin treatment in patients undergoing dialysis did not reduce cardiovascular events or mortality[3,4]. Nevertheless, statin therapy could be continued if a patient was already receiving it, although specific

Correspondence to:

Kurathong S.

Faculty of Medicine Vajira Hospital, Navamindradhiraj University, 681 Samsen Road, Dusit, Bangkok 10300, Thailand.

Phone: +66-2-2443000

Email: sathit@nmu.ac.th

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recommendations for patients undergoing dialysis are not provided, consistent with the 2024 KDIGO guidelines[5]. Therefore, the management of dyslipidemia in patients undergoing dialysis remains controversial.

Fibrates have been reported to be effective in managing mixed dyslipidemia, which is a prevalent condition in patients with ESKD, with reductions of approximately 10% in cholesterol levels and 40% to 55% in triglyceride levels. However, the overall efficacy of fibrates in consistently lowering cholesterol and triglycerides in patients undergoing dialysis remains uncertain. Fenofibrate was previously contraindicated or used with caution in patients with advanced CKD due to concerns about potential adverse effects[6-8]. However, recent evidence has demonstrated the safety and efficacy of low-dose fenofibrate in this population. Makowka et al. reported significant reductions in cholesterol and triglyceride levels among patients undergoing dialysis treated with fenofibrate, without significant adverse effects[9]. Built upon these findings, another study showed that the continued use of fenofibrate may offer cardiovascular protective effects in patients with advanced CKD compared with statins and may delay the need for permanent dialysis[10].

Additionally, a randomized study comparing fenofibrate with placebo showed that fenofibrate use was associated with a reduced incidence of albuminuria and a slower decline in the estimated glomerular filtration rate (eGFR[11]. Fenofibrate combined with high-intensity statins has also been shown to provide additional cardiovascular benefits. Moreover, emerging data have shown that the recent and continuous use of fibrates is associated with a reduced risk of major adverse cardiovascular events in patients with CKD, highlighting the potential advantages of sustained fibrate therapy in this population[12].

The present study aimed to evaluate the lipid-lowering effects and safety profile of fibrates, particularly fenofibrate and gemfibrozil, in patients undergoing dialysis. These two fibrates were chosen for investigation because they are the only fibrates included in the national essential medicine list. Furthermore, the present study aimed to investigate changes in fasting blood lipid levels after the administration of fenofibrate or gemfibrozil and evaluate the incidence of complications and discontinuation rate of fibrate therapy in patients with ESKD undergoing dialysis.

Materials and Methods

Study design

This retrospective cohort study included patients undergoing dialysis (ICD-10 code N185) who were treated with fenofibrate or gemfibrozil. Data were obtained from the Electronic Hospital Information System at Vajira Hospital. Baseline demographic and clinical data were extracted from patient records to assess changes in blood lipid levels. The study was conducted until data collection was complete for 80 patients, as determined by the calculated sample size. Given the retrospective nature of the study, the follow-up period ranged from 6 to 12 months, depending on the availability of clinical records for each patient. Lipid profiles were evaluated by recording the final measurement prior to the initiation of fibrate therapy and subsequent measurements taken between 6 and 12 months post-treatment. The mean value was used if multiple measurements were available during the follow-up period.

Adverse effects were documented from outpatient records and patient-reported symptoms. CPK levels were measured only in patients with suspected myopathy. Hepatitis was diagnosed based on elevated liver enzymes (AST/ALT >2 times the upper limit of normal) and clinical symptoms consistent with hepatic injury.

Participants

During the study period, data were collected from 116 patients with ESKD who received fibrate therapy. Inclusion criteria consisted of patients aged 18 to 80 years who received fenofibrate or gemfibrozil between January 2012 and December 2018, were diagnosed with chronic kidney disease (CKD) undergoing hemodialysis or peritoneal dialysis for at least 6 months, and had documented lipid profile measurements at least once within 6 months prior to fibrate therapy initiation and at least once between 6 and 8 months after therapy initiation.

Exclusion criteria included patients who were administered additional lipid-modifying agents other than statins or ezetimibe, those who underwent dose adjustments of such agents during the study period, those with unstable clinical conditions such as acute illnesses or hospitalizations, those who underwent renal transplantation or modified their dialysis modality, and those who experienced unplanned hospitalizations, clinic visits, or emergency department visits during the study period.

The study was approved by the Human Research Ethics Committee of Vajira Hospital (084/2557). Data collection was conducted in compliance with ethical guidelines. Ethical approval was granted in 2014, with a review of pre-existing data from earlier years.

Statistical analysis

Data were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Changes in fasting blood cholesterol and triglyceride levels before and after treatment with fenofibrate or gemfibrozil were presented as mean ± standard deviation and compared using paired t-tests. Baseline demographic data were expressed as percentages. Cases with missing critical data were excluded from the

analysis. Statistical significance was set at $p<0.05$ for all tests.

Results

Of the 116 patients enrolled in this study, 32 were excluded due to concurrent medication use, unstable conditions, or incomplete data. Finally, 84 eligible patients were included in the analysis (Figure 1). Of the 84 patients, 26 received fenofibrate, and 58 received gemfibrozil. The majority of patients were male (57.7% in the fenofibrate group and 60.3% in the gemfibrozil group), with a mean age of 56.8±13.5 years in the fenofibrate group and 59.5±9.9 years in the gemfibrozil group. The fenofibrate group had a higher average body mass index (25.9±7.3 kg/m²) than the gemfibrozil group (23.8±6.2 kg/m²). Initial lipid profiles showed higher baseline cholesterol (231±64 mg/dl vs. 218±82 mg/dl) and triglyceride levels (289±216 mg/dl vs. 301±186 mg/dl) in the fenofibrate group than in the gemfibrozil group (Table 1).

Statistically significant reductions in triglyceride levels were observed in both groups after 6 months of fibrate therapy. The gemfibrozil group showed a decrease from 301±186 mg/dl to 216±162 mg/dl (mean change: 85±54 mg/dl, p=0.01), and the fenofibrate group showed a decrease from 289±216 mg/dl to 182±151 mg/dl (mean change: 107±72 mg/dl, p=0.03). However, no statistically significant difference in the reduction of cholesterol levels was observed between the two groups. The gemfibrozil group showed a decrease in cholesterol levels from 218±82 mg/dl to 207±81 mg/dl (mean change: 11±5.1 mg/dl, p=0.06), whereas the fenofibrate group showed a decrease from 231±64 mg/dl to 203±61 mg/dl (mean change: 28±8.1 mg/dl, p=0.07). The between-group comparison of cholesterol reduction showed no statistically significant difference (p=0.18). No significant changes in high-density lipoprotein levels were observed in either group, with the gemfibrozil group showing a decrease in high-density lipoprotein from 39±11 mg/dl to 37±11 mg/dl (mean change: 2±0.8 mg/dl, p=0.15) and the fenofibrate group showing a decrease from 37±18 mg/dl to 36±16 mg/dl (mean change: 1±0.4 mg/dl, p=0.24) (Table 2).

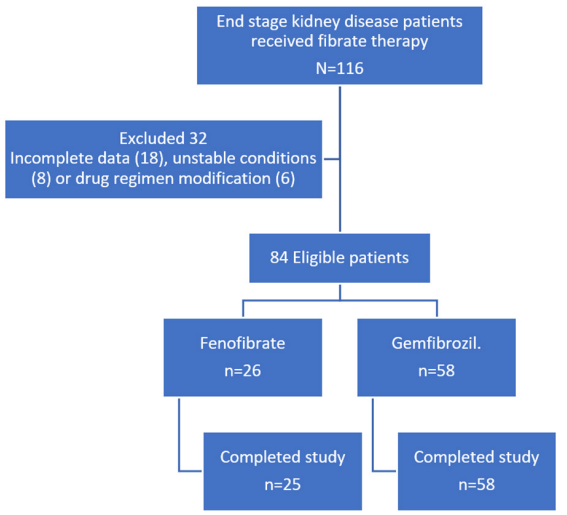

Figure 1. Participant flow diagram.

During the study period, 8 deaths were recorded: 3 in the fenofibrate group (11.5%) due to sudden death (2 cases, 7.7%) and fatal stroke (1 case, 3.8%) and 5 in the gemfibrozil group (8.6%) due to sudden death (1 case, 1.7%), fatal ischemic heart disease (2 cases, 3.4%), fatal stroke (1 case, 1.7%), and sepsis (1 case, 1.7%). Other observed adverse effects included muscle pain in 4 patients (15.4%) in the fenofibrate group, with 1 case (3.8%) being severe enough to necessitate discontinuation of the medication (fenofibrate 200 mg combined with atorvastatin). Muscle pain was observed in 2 patients (3.4%) in the gemfibrozil group. No cases of creatine kinase elevation >200 U/L, rhabdomyolysis, or hepatitis were reported in either group (Table 3).

Discussion

The present study evaluated the lipid-lowering effects and safety profiles of fenofibrate and gemfibrozil in patients with ESKD undergoing dialysis. The results showed that both fibrates effectively reduced triglyceride levels in this population, consistent with their known pharmacological actions. The gemfibrozil group showed a 37% reduction in triglyceride levels, whereas the fenofibrate group showed a 28% reduction. Although these reductions were substantial, no statistically significant difference in triglyceride-lowering efficacy was observed between the groups (p=0.24). Furthermore, cholesterol reduction was modest in both groups, with a 5% decrease in the gemfibrozil group and a 12% decrease in the fenofibrate group, and no statistically significant difference was observed between the two groups (p=0.18). These findings are consistent with those of previous studies, indicating that fibrates have limited efficacy in lowering cholesterol levels in patients with ESKD.

The limited sample size, particularly in the fenofibrate group, constitutes a significant limitation, potentially reducing the statistical power and affecting the generalizability of the findings. This constraint has been recognized as a factor that may compromise the external validity of the study. Moreover, the exclusion of patients with unstable clinical conditions may have resulted in an underestimation of the true incidence of adverse effects. This limitation emphasizes the need for future studies with broader inclusion criteria to provide a more comprehensive

Table 1. Baseline characteristics of patients

	Fenofibrate (n=26)	Gemfibrozil (n=58)	p-value
Male, n (%)	15 (57.7%)	35 (60.3%)	
Age, mean ± SD (years)	56.8±13.5	59.5±9.9	0.45
Body Mass Index, mean ± SD (kg/m^2)	25.9±7.3	23.8±6.2	0.33
Dialysis Vintage, mean ± SD (years)	6.3±5.5	6.5±5.7	0.82
Serum creatinine (mg/dl)	7.91±4.13	8.44±4.35	0.69
eGFR, mean ± SD (ml/min/1.73 m^2)	8.5±5.3	8.3±5.1	0.92
Systolic Blood Pressure , mean ± SD (mmHg)	152±28	155±24	0.71
Diastolic Blood Pressure , mean ± SD (mmHg)	70±15	72±12	0.66
Comorbidities, n (%)			
Ischemic heart disease	6 (23%)	15 (25.9%)	
Cerebrovascular disease	4 (15.4%)	8 (13.8%)	
Peripheral artery disease	0	2 (3.4%)	
Diabetes mellitus	14 (53.8%)	24 (41.4%)	
Baseline Cholesterol, mean ± SD (mg/dl)	231±64	218±82	0.57
Baseline LDL-cholesterol, mean ± SD (mg/dl)	118±53	122±48	0.77
Baseline Triglyceride, mean ± SD (mg/dl)	289±216	301±186	0.82
Baseline Glycated Hemoglobin, mean ± SD (%)	6.3±1.9	6.1±1.7	0.74
Concomitant Medications, n (%)			
Statin	22 (84.6%)	42 (72.4%)	
Angiotensin receptor antagonists	11 (42.3%)	24 (41.4%)	
ACE inhibitors	5 (19.2%)	9 (15.5%)	
Calcium antagonists	20 (76.9%)	42 (72.4%)	
Antiplatelet	14 (53.8%)	26 (44.8%)	
Other lipid-lowering drugs, n (%)			
Simvastatin	7 (26.9%)	1 (1.7%)	
Atorvastatin	12 (46.2%)	27 (46.5%)	
Mevalotin	1 (3.8%)	4 (6.9%)	
Fluvastatin	0	2 (3.4%)	
Pitavastatin	2 (7.7%)	8 (13.8%)	
Ezetimibe	5 (19.2%)	10 (17.2%)	
Drug dose, daily: n (%)	100 mg: 15 (57.7%)	300 mg: 5 (8.6%)	
	145 mg: 3 (11.5%)	600 mg: 34 (58.6%)	
	160 mg: 3 (11.5%)	1,200 mg:19 (32.8%)	
	200 mg: 5 (19.2%)		

Table 2. Lipid level changes after lipid-lowering medication

Mean ± SD (mg/dl)	Fenofibrate (F)			Gemfibrozil (G)			Between group		
	Baseline	Follow-up	p-value	Baseline	Follow-up	p-value	F group change	G group change	p-value
Cholesterol	231±64	203±61	0.07	218±82	207±81	0.06	28±8.1	11±5.1	0.18
Triglyceride	301±186	216±162	0.01	289±216	182±151	0.03	107±72	85±54	0.24
HDL	37±18	36±16	0.24	39±11	37±11	0.15	1±0.4	2±0.8	0.43

assessment of the safety profile of fibrates in this population.

The observed differences in triglyceride reduction between the two groups might be attributable to the dosing strategies used. Fenofibrate was administered at a dose lower than the standard gemfibrozil dose. Despite the lower dosage, fenofibrate achieved a cholesterol-lowering effect comparable to that of gemfibrozil, indicating that it may offer similar lipid-modifying benefits even at reduced doses. These findings highlight the potential utility of fenofibrate as a viable treatment option for dyslipidemia in patients

Table 3. Adverse effects of both lipid-lowering groups

	Fenofibrate (n=26)		Gemfibrozil (n=58)	
	n	%	n	%
Death	3	11.5%	5	8.6%
Sudden death	2	7.7%	1	1.7%
Fatal ischemic heart disease	0	-	2	3.4%
Fatal stroke	1	3.8%	1	1.7%
Sepsis	0	-	1	1.7%
Myalgia	4	15.4%	2	3.4%
Discontinuation	1	3.8%	0	-
CK >200	0	-	0	-
Rhabdomyolysis	0	-	0	-
Hepatitis	0	-	0	-

with ESKD, particularly when a lower dose is desired to minimize adverse effects.

Fibrates, particularly fenofibrate and gemfibrozil, are well-established lipid-lowering agents, primarily targeting hypertriglyceridemia. Given the high prevalence of dyslipidemia in hemodialysis patients, fibrates provide an alternative to statins, which have shown limited cardiovascular benefits in this population. The efficacy of fibrates in reducing triglyceride levels is well-documented, with previous studies demonstrating a significant decrease in triglycerides among patients with CKD and ESKD. Our findings align with this evidence, indicating that both fenofibrate and gemfibrozil significantly lower triglyceride levels in dialysis patients. Additionally, fenofibrate demonstrated a comparable cholesterol-lowering effect despite being used at a lower dose, suggesting that it may offer a favorable lipid-modifying profile in this population.

While fibrates are primarily indicated for hypertriglyceridemia, emerging evidence suggests they may also confer additional benefits beyond lipid modulation. Studies have indicated that fenofibrate may reduce albuminuria and slow the decline in estimated glomerular filtration rate (eGFR), suggesting potential nephroprotective effects. Although our study did not directly assess renal outcomes, the observed lipid changes support the role of fibrates in managing dyslipidemia in dialysis patients, warranting further investigation into their potential renal and cardiovascular benefits.

The safety profile of both medications was favorable. The incidence of adverse effects was relatively low. Muscle pain was the most frequently reported side effect, occurring in 15.4% of patients in the fenofibrate group and 3.4% in the gemfibrozil group. Only 1 patient (3.8%) in the fenofibrate group discontinued therapy due to severe muscle pain, and no cases of creatine kinase elevation, rhabdomyolysis, or hepatitis were reported in either group. This is particularly significant given the historical concerns about the use of fibrates in the dialysis population due to potential adverse effects.

Previous concerns regarding fibrate therapy in dialysis patients primarily stem from the risk of myopathy, hepatotoxicity, and drug accumulation due to impaired renal clearance. However, our study supports growing evidence that low-dose fenofibrate is well-tolerated in hemodialysis patients. Notably, no cases of rhabdomyolysis were reported, contradicting prior apprehensions about its safety in this population. Additionally, gemfibrozil, which is known to have a lower risk of renal accumulation, was similarly well-tolerated, reinforcing the feasibility of fibrate use in patients with ESKD.

Drug modifications during the study were primarily due to adverse effects or clinical judgment rather than treatment failure. This reflects the individualized and cautious approach required for managing dyslipidemia in this high-risk population.

The mortality rates were comparable between the two groups. Three deaths (11.5%) occurred in the fenofibrate group, and five deaths (8.6%) occurred in the gemfibrozil group. The causes of death included sudden cardiac arrest, stroke, ischemic heart disease, and sepsis, indicating a high baseline cardiovascular risk in this population. However, the number of deaths was too small to allow meaningful analysis or attribute directly to the lipid-lowering agents. These findings indicate that fenofibrate and gemfibrozil are relatively safe for dyslipidemia management in patients undergoing dialysis. However, further studies are needed to clarify the effects of fenofibrate and gemfibrozil on mortality.

The present study findings are consistent with those of previous studies, which showed that ongoing therapy with fenofibrate in patients with advanced CKD may offer cardiovascular protection comparable to that provided by statins and may delay progression to permanent dialysis[10]. Furthermore, fenofibrate combined with high-intensity statins could confer additional benefits in terms of cardiovascular risk reduction. Additionally, the present study aligns with evidence from other studies that showed that randomization to fenofibrate was associated with lower rates of incident albuminuria and a slower decline in eGFR[11], highlighting its potential renal protective effects.

Fibrates have become an alternative therapeutic option for patients with ESKD, particularly given that current guidelines do not recommend statins for patients with ESKD due to the minimal cardiovascular benefits observed in major trials[3,4]. The study findings indicate that low-dose fibrate therapy, particularly fenofibrate, is a viable and safe alternative for lipid management in patients with ESKD. Notably, fenofibrate can be safely coadministered with simvastatin, unlike gemfibrozil, which cannot be used

concomitantly due to the risk of myopathy.

The results of the present study support the utility of low-dose fenofibrate as an effective and safe strategy for managing hypertriglyceridemia in patients with ESKD undergoing dialysis. Although previous guidelines have cautioned against the use of low-dose fenofibrate in patients with advanced CKD[7-9], our results showed that low-dose fenofibrate provided meaningful lipid-lowering effects with minimal risk of adverse effects. Low-dose fenofibrate is a promising alternative to statins, which have limited efficacy in this population, as demonstrated in trials[3,4]. Further larger, prospective studies are needed to investigate the potential benefits of low-dose fenofibrate in reducing cardiovascular events, delaying dialysis initiation, and mitigating renal function decline to confirm these findings and refine treatment guidelines for dyslipidemia in patients with ESKD.

Conclusion

Fibrate therapy effectively reduces triglyceride levels in patients with CKD undergoing dialysis, with no significant adverse effects reported. These findings support the consideration of fibrates as an effective complementary therapeutic option for dyslipidemia management, particularly for triglyceride reduction, rather than replacing statins in this population.

What is already known on this topic?

Fibrates, such as fenofibrate and gemfibrozil, can effectively lower triglyceride levels in patients with dyslipidemia, including those with advanced chronic kidney disease. However, the safety and efficacy of fibrates in patients undergoing dialysis remain debated due to concerns about their potential adverse effects and limited evidence supporting their impact on overall cardiovascular outcomes.

What this study adds?

The present study demonstrated that low-dose fenofibrate and gemfibrozil effectively reduced triglyceride levels in patients undergoing dialysis without significant adverse effects, highlighting their potential as safe and effective alternatives to statins, which have limited efficacy in this population. While fenofibrate achieved lipid-lowering effects comparable to gemfibrozil, even at reduced doses, and previous studies have suggested potential cardiovascular protection and delayed dialysis initiation, these findings should be interpreted with caution. Further prospective investigations are necessary to validate these observations and assess long-term clinical outcomes.

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Conflicts of interest

The authors declare no conflict of interest.

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