

Change in LDL-C and Non-HDL-C After Addition of Bempedoic Acid to Stable Statin Therapy: A Retrospective Study at a Government Hospital in Telangana

Danam Sharon Ramani¹, Sabari Balaji², Marri Neha³

^{1,2,3}Junior Resident, Department of Pharmacology, Osmania Medical College, Hyderabad, Telangana, India

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Corresponding author: Dr. Danam Sharon Ramani

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Abstract

Introduction: Persistent elevation of low-density lipoprotein cholesterol (LDL-C) despite statin therapy remains a common challenge in dyslipidemia management. Bempedoic acid provides an additional lipid-lowering option through inhibition of ATP-citrate lyase. This study evaluated changes in LDL-C and non-high-density lipoprotein cholesterol (non-HDL-C) following its addition to stable statin therapy.

Materials and Methods: This retrospective comparative study included 60 adults with dyslipidemia receiving stable statin therapy at a government hospital in Telangana. Patients were divided into a bempedoic acid group (n=30), receiving bempedoic acid 180 mg once daily in addition to statin therapy, and a control group (n=30), continuing statin therapy alone. Lipid parameters were assessed at baseline and after 12 weeks. The primary outcomes were absolute and percentage changes in LDL-C and non-HDL-C.

Results: Baseline lipid parameters were comparable between the groups. At 12 weeks, mean LDL-C decreased from 129.4±26.1 to 105.2±24.5 mg/dL in the bempedoic acid group, compared with 127.8±25.7 to 125.9±25.1 mg/dL in controls. The percentage reduction was 18.7% versus 1.5%, respectively (p<0.001). Non-HDL-C decreased by 13.3% in the bempedoic acid group compared with 1.2% in controls (p<0.001). No serious adverse events were observed.

Conclusion: Addition of bempedoic acid to stable statin therapy was associated with significantly greater reductions in LDL-C and non-HDL-C over 12 weeks compared with statin therapy alone.

Keywords: Bempedoic acid; LDL cholesterol; Non-HDL cholesterol; Dyslipidemia; Statin therapy.

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Introduction

Dyslipidemia, particularly elevated low-density lipoprotein cholesterol (LDL-C), is a major modifiable risk factor for atherosclerotic cardiovascular disease (ASCVD) [1]. Reduction of circulating LDL-C is associated with a lower risk of cardiovascular events, and statins remain the foundation of pharmacological lipid-lowering therapy [2]. However, despite appropriate statin treatment, a considerable proportion of patients fail to achieve adequate LDL-C reduction or remain above their individualized treatment targets [3]. This residual elevation of atherogenic cholesterol creates a need for additional lipid-lowering strategies, particularly in patients at high or very high cardiovascular risk [4].

Bempedoic acid is an orally administered lipid-lowering agent that inhibits ATP-citrate lyase (ACL), an enzyme involved in hepatic cholesterol synthesis upstream of 3-hydroxy-3-methylglutaryl-

coenzyme A reductase [5]. Its mechanism is complementary to that of statins and allows further reduction in LDL-C when added to existing statin therapy [6]. Clinical trials have demonstrated that bempedoic acid provides additional LDL-C lowering when administered in patients receiving maximally tolerated statin therapy [7]. Its mechanism of action and hepatic activation also provide a therapeutic option for patients who require additional LDL-C reduction, including those who are unable to achieve adequate control with statins alone [8].

In addition to LDL-C, non-high-density lipoprotein cholesterol (non-HDL-C) is an important marker of the overall burden of atherogenic lipoproteins [9]. Non-HDL-C incorporates cholesterol carried by LDL and other atherogenic particles and can therefore provide complementary information regarding residual lipid-related cardiovascular risk

[10]. Evaluation of both LDL-C and non-HDL-C may provide a broader assessment of the lipid-lowering effect achieved following addition of bempedoic acid to background statin therapy [11].

Although the efficacy of bempedoic acid has been evaluated extensively in randomized clinical trials, real-world evidence from routine clinical practice, particularly from Indian government hospital settings, remains comparatively limited. Retrospective comparative studies can provide useful information regarding the lipid response observed among patients treated under routine clinical conditions. Therefore, the present study was undertaken to compare changes in LDL-C and non-HDL-C over 12 weeks between patients receiving stable statin therapy with and without the addition of bempedoic acid. The study aimed to compare the change in LDL-C and non-HDL-C levels after 12 weeks among patients receiving stable statin therapy with and without addition of bempedoic acid.

Material and Methods

This retrospective comparative observational study was conducted at a government hospital in Telangana, India, to evaluate the change in low-density lipoprotein cholesterol (LDL-C) and non-high-density lipoprotein cholesterol (non-HDL-C) following addition of bempedoic acid to stable statin therapy. Medical records of adult patients with dyslipidemia who were receiving stable statin therapy and had available lipid profile measurements at baseline and 12 weeks were reviewed. A total of 60 patients were included and divided into two groups of 30 patients each: the bempedoic acid group, comprising patients who received bempedoic acid 180 mg once daily in addition to their existing statin therapy, and the control group, comprising patients who continued stable statin therapy without addition of bempedoic acid. The observation period was 12 weeks.

Patients aged ≥ 18 years with documented dyslipidemia, stable statin therapy before study entry, and available lipid profile data at baseline and approximately 12 weeks were eligible for inclusion. Patients were excluded if they had incomplete baseline or follow-up lipid data, changes in statin dose during the 12-week period, initiation of another lipid-lowering medication during follow-up, or insufficient clinical information for analysis. Baseline demographic and

clinical variables including age, sex, body mass index, diabetes mellitus, hypertension, cardiovascular disease, smoking status, and type and dose of statin therapy were extracted from the medical records.

Lipid parameters including total cholesterol, LDL-C, HDL-C and triglycerides were recorded at baseline and after 12 weeks. Non-HDL-C was calculated as total cholesterol minus HDL-C. The primary outcomes were the absolute and percentage changes in LDL-C and non-HDL-C from baseline to 12 weeks. Secondary outcomes included changes in total cholesterol, HDL-C and triglycerides, the proportion of patients achieving LDL-C < 100 mg/dL, and the distribution of patients according to percentage reduction in LDL-C. Documented adverse events during the 12-week follow-up period were also recorded.

Continuous variables were expressed as mean $\pm$ standard deviation (SD), while categorical variables were presented as frequency and percentage [n (%)]. Baseline characteristics and lipid parameters were compared between the two groups using the independent-samples t-test for normally distributed continuous variables and the chi-square test or Fisher's exact test for categorical variables, as appropriate. Within-group changes from baseline to 12 weeks were assessed using the paired t-test, while between-group differences in change were assessed using an independent-samples t-test. Percentage change was calculated as $[(12\text{-week value} - \text{baseline value}) / \text{baseline value}] \times 100$. A two-sided p-value < 0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA).

Results

The study included 60 patients, with 30 patients in the bempedoic acid group and 30 patients in the control group. The age distribution was comparable between the two groups, with the majority of participants aged 50–69 years. Males constituted 63.3% of the bempedoic acid group and 60.0% of the control group. Diabetes mellitus was present in 53.3% and 50.0% of patients, respectively, while hypertension was reported in 63.3% of both groups. Established cardiovascular disease was present in 40.0% of participants in each group. Current smoking was reported by 20.0% of patients in both groups. (Table 1)

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Bempedoic acid group (n=30), n (%)	Control group (n=30), n (%)	Total (N=60), n (%)
Age (years)			
18–39	2 (6.7)	2 (6.7)	4 (6.7)
40–49	6 (20.0)	6 (20.0)	12 (20.0)
50–59	9 (30.0)	9 (30.0)	18 (30.0)
60–69	10 (33.3)	9 (30.0)	19 (31.7)
≥70	3 (10.0)	4 (13.3)	7 (11.7)
Sex			
Male	19 (63.3)	18 (60.0)	37 (61.7)
Female	11 (36.7)	12 (40.0)	23 (38.3)
Diabetes mellitus	16 (53.3)	15 (50.0)	31 (51.7)
Hypertension	19 (63.3)	19 (63.3)	38 (63.3)
Established cardiovascular disease	12 (40.0)	12 (40.0)	24 (40.0)
Current smoking	6 (20.0)	6 (20.0)	12 (20.0)

The mean age was 58.1 ± 9.5 years in the bempedoic acid group and 58.7 ± 10.0 years in the control group. The mean BMI was 27.2 ± 3.5 kg/m² and 27.0 ± 3.7 kg/m², respectively. Mean systolic blood pressure was 132.4 ± 14.1 mmHg in the bempedoic acid group compared with 131.8 ± 13.7

mmHg in the control group, while mean diastolic blood pressure was 81.6 ± 8.2 and 80.9 ± 7.9 mmHg, respectively. The baseline clinical characteristics were comparable between the two groups. (Table 2)

Table 2: Age, BMI and Baseline Clinical Characteristics

Parameter	Bempedoic acid group (n=30), mean $\pm$ SD	Control group (n=30), mean $\pm$ SD	p-value
Age (years)	58.1 ± 9.5	58.7 ± 10.0	0.812
BMI (kg/m ²)	27.2 ± 3.5	27.0 ± 3.7	0.835
Systolic BP (mmHg)	132.4 ± 14.1	131.8 ± 13.7	0.868
Diastolic BP (mmHg)	81.6 ± 8.2	80.9 ± 7.9	0.739

The distribution of background statin therapy was similar between the groups. Atorvastatin 20 mg/day was the most frequently used regimen, accounting for 30.0% of patients in each group, followed by atorvastatin 40 mg/day in 16.7% of each group.

Rosuvastatin 10 mg/day was used in 13.3% of the bempedoic acid group and 16.7% of the control group. The remaining participants received atorvastatin 10 mg/day, rosuvastatin 5 mg/day, or rosuvastatin 20 mg/day. (Table 3)

Table 3: Baseline Statin Therapy in the Study Groups

Statin therapy	Bempedoic acid group (n=30), n (%)	Control group (n=30), n (%)	Total, n (%)
Atorvastatin 10 mg/day	6 (20.0)	6 (20.0)	12 (20.0)
Atorvastatin 20 mg/day	9 (30.0)	9 (30.0)	18 (30.0)
Atorvastatin 40 mg/day	5 (16.7)	5 (16.7)	10 (16.7)
Rosuvastatin 5 mg/day	4 (13.3)	3 (10.0)	7 (11.7)
Rosuvastatin 10 mg/day	4 (13.3)	5 (16.7)	9 (15.0)
Rosuvastatin 20 mg/day	2 (6.7)	2 (6.7)	4 (6.7)
Total	30 (100.0)	30 (100.0)	60 (100.0)

At baseline, the mean LDL-C was 129.4 ± 26.1 mg/dL in the bempedoic acid group and 127.8 ± 25.7 mg/dL in the control group. Mean non-HDL-C was 158.9 ± 30.5 mg/dL and 156.7 ± 29.8 mg/dL, respectively. Mean total cholesterol, HDL-C, and triglyceride levels were also comparable between the groups at baseline, indicating similar lipid profiles before the 12-week observation period. (Table 4)

Table 4: Comparison of Lipid Parameters at Baseline

Lipid parameter	Bempedoic acid group (n=30), mean $\pm$ SD	Control group (n=30), mean $\pm$ SD	p-value
LDL-C (mg/dL)	129.4 $\pm$ 26.1	127.8 $\pm$ 25.7	0.812
Non-HDL-C (mg/dL)	158.9 $\pm$ 30.5	156.7 $\pm$ 29.8	0.778
Total cholesterol (mg/dL)	199.4 $\pm$ 34.8	197.6 $\pm$ 33.7	0.839
HDL-C (mg/dL)	40.6 $\pm$ 8.0	40.8 $\pm$ 8.2	0.924
Triglycerides (mg/dL)	155.8 $\pm$ 62.1	153.4 $\pm$ 60.8	0.881

At 12 weeks, the mean LDL-C was 105.2 $\pm$ 24.5 mg/dL in the bempedoic acid group compared with 125.9 $\pm$ 25.1 mg/dL in the control group. Mean non-HDL-C was 137.8 $\pm$ 28.5 mg/dL in the bempedoic acid group and 154.9 $\pm$ 29.7 mg/dL in

the control group. Total cholesterol was 178.8 $\pm$ 32.0 mg/dL and 195.2 $\pm$ 33.4 mg/dL, respectively. HDL-C showed minimal differences between groups, while triglyceride levels remained broadly comparable. (Table 5)

Table 5: Comparison of Lipid Parameters at 12 Weeks

Lipid parameter	Bempedoic acid group (n=30), mean $\pm$ SD	Control group (n=30), mean $\pm$ SD	p-value
LDL-C (mg/dL)	105.2 $\pm$ 24.5	125.9 $\pm$ 25.1	<0.001
Non-HDL-C (mg/dL)	137.8 $\pm$ 28.5	154.9 $\pm$ 29.7	0.025
Total cholesterol (mg/dL)	178.8 $\pm$ 32.0	195.2 $\pm$ 33.4	0.057
HDL-C (mg/dL)	42.0 $\pm$ 8.3	40.9 $\pm$ 8.1	0.606
Triglycerides (mg/dL)	151.1 $\pm$ 59.2	154.7 $\pm$ 61.0	0.818

Within the bempedoic acid group, mean LDL-C decreased from 129.4 $\pm$ 26.1 mg/dL at baseline to 105.2 $\pm$ 24.5 mg/dL at 12 weeks, while non-HDL-C decreased from 158.9 $\pm$ 30.5 mg/dL to 137.8 $\pm$ 28.5 mg/dL. In comparison, the control group showed relatively little change in LDL-C, from 127.8 $\pm$ 25.7 mg/dL to 125.9 $\pm$ 25.1 mg/dL, and non-HDL-C, from 156.7 $\pm$ 29.8 mg/dL to 154.9 $\pm$ 29.7 mg/dL. (Table 6)

Table 6: Within-Group Change in LDL-C and Non-HDL-C Over 12 Weeks

Parameter	Bempedoic acid group: Baseline	Bempedoic acid group: 12 weeks	Control group: Baseline	Control group: 12 weeks
LDL-C (mg/dL)	129.4 $\pm$ 26.1	105.2 $\pm$ 24.5	127.8 $\pm$ 25.7	125.9 $\pm$ 25.1
Non-HDL-C (mg/dL)	158.9 $\pm$ 30.5	137.8 $\pm$ 28.5	156.7 $\pm$ 29.8	154.9 $\pm$ 29.7

The mean absolute reduction in LDL-C was 24.2 mg/dL in the bempedoic acid group compared with 1.9 mg/dL in the control group. Correspondingly, the mean percentage reduction in LDL-C was 18.7% in the bempedoic acid group compared with 1.5% in the control group, demonstrating a substantially greater reduction following addition of bempedoic acid. (Table 7)

Table 7: Comparison of Absolute and Percentage Change in LDL-C

Outcome	Bempedoic acid group (n=30)	Control group (n=30)	Between-group p-value
Baseline LDL-C (mg/dL)	129.4 $\pm$ 26.1	127.8 $\pm$ 25.7	0.812
12-week LDL-C (mg/dL)	105.2 $\pm$ 24.5	125.9 $\pm$ 25.1	<0.001
Absolute change (mg/dL)	-24.2 $\pm$ 12.8	-1.9 $\pm$ 10.6	<0.001
Percentage change (%)	-18.7 $\pm$ 9.3	-1.5 $\pm$ 8.4	<0.001

The mean absolute reduction in non-HDL-C was 21.1 mg/dL in the bempedoic acid group compared with 1.8 mg/dL in the control group. The corresponding percentage reduction was 13.3% in the bempedoic acid group and 1.2% in the control group. Thus, the reduction in non-HDL-C was greater among patients receiving bempedoic acid in addition to stable statin therapy. (Table 8)

Table 8: Comparison of Absolute and Percentage Change in Non-HDL-C

Outcome	Bempedoic acid group (n=30)	Control group (n=30)	Between-group p-value
Baseline non-HDL-C (mg/dL)	158.9 $\pm$ 30.5	156.7 $\pm$ 29.8	0.778
12-week non-HDL-C (mg/dL)	137.8 $\pm$ 28.5	154.9 $\pm$ 29.7	0.025
Absolute change (mg/dL)	-21.1 $\pm$ 15.2	-1.8 $\pm$ 13.7	<0.001
Percentage change (%)	-13.3 $\pm$ 9.1	-1.2 $\pm$ 8.7	<0.001

Among patients receiving bempedoic acid, 33.3% demonstrated a 10–19.9% reduction in LDL-C and another 33.3% achieved a 20–29.9% reduction. A reduction of $\geq 30\%$ was observed in 16.7% of patients. In the control group, 60.0% had less than a 5% reduction in LDL-C, while only 6.7% achieved a 20–29.9% reduction and none achieved a reduction of $\geq 30\%$. (Table 9)

Table 9: Distribution of Patients According to Percentage Reduction in LDL-C

Percentage reduction in LDL-C	Bempedoic acid group (n=30), n (%)	Control group (n=30), n (%)
<5%	2 (6.7)	18 (60.0)
5–9.9%	3 (10.0)	6 (20.0)
10–19.9%	10 (33.3)	4 (13.3)
20–29.9%	10 (33.3)	2 (6.7)
$\geq 30\%$	5 (16.7)	0 (0.0)
Total	30 (100.0)	30 (100.0)

At 12 weeks, an LDL-C level below 100 mg/dL was achieved by 43.3% of patients in the bempedoic acid group compared with 16.7% in the control group. Conversely, LDL-C remained ≥ 100 mg/dL in 56.7% of patients receiving bempedoic acid and 83.3% of control patients. (Table 10)

Table 10: Achievement of LDL-C <100 mg/dL at 12 Weeks

LDL-C category	Bempedoic acid group, n (%)	Control group, n (%)
<100 mg/dL	13 (43.3)	5 (16.7)
≥ 100 mg/dL	17 (56.7)	25 (83.3)
Total	30 (100.0)	30 (100.0)

Among patients with diabetes mellitus, the mean percentage change in LDL-C was $-19.5 \pm 9.1\%$ in the bempedoic acid group compared with $-1.8 \pm 8.2\%$ in the control group. Among patients without diabetes, the corresponding reduction was $-17.8 \pm 9.5\%$ and $-1.2 \pm 8.6\%$, respectively. Thus, LDL-C reduction was observed in both diabetic and non-diabetic patients receiving bempedoic acid. (Table 11)

Table 11: Change in LDL-C According to Diabetes Status

Diabetes status	Bempedoic acid group: % change in LDL-C	Control group: % change in LDL-C	p-value
Diabetes present	-19.5 ± 9.1	-1.8 ± 8.2	<0.001
Diabetes absent	-17.8 ± 9.5	-1.2 ± 8.6	<0.001

Adverse events were reported in 13.3% of patients receiving bempedoic acid compared with 6.7% of control patients.

Hyperuricemia was reported in 6.7% of patients in the bempedoic acid group and was not documented in the control group. Myalgia occurred in 3.3% of

patients in each group, while arthralgia was reported in 3.3% of the bempedoic acid group.

One patient (3.3%) receiving bempedoic acid discontinued treatment because of an adverse event. No serious adverse events were reported in either group. (Table 12)

Table 12: Adverse Events During 12-Week Follow-up

Adverse event	Bempedoic acid group (n=30), n (%)	Control group (n=30), n (%)
Hyperuricemia	2 (6.7)	0 (0.0)
Myalgia	1 (3.3)	1 (3.3)
Arthralgia	1 (3.3)	0 (0.0)
Headache	0 (0.0)	1 (3.3)
Total	30 (100.0)	30 (100.0)

Discussion

In the present comparative study, addition of bempedoic acid 180 mg once daily to stable statin therapy was associated with a substantially greater reduction in LDL-C over 12 weeks than continuation of statin therapy alone. Mean LDL-C decreased from 129.4 ± 26.1 mg/dL to 105.2 ± 24.5 mg/dL in the bempedoic acid group, corresponding to an 18.7% reduction, whereas the control group showed a reduction of only 1.5%. The between-

group difference was statistically significant ($p < 0.001$).

These findings are consistent with the CLEAR Harmony trial, in which bempedoic acid added to maximally tolerated statin therapy produced a 16.5% reduction in LDL-C at week 12, with a placebo-corrected difference of 18.1 percentage points [12]. The magnitude of LDL-C reduction in the present study was also comparable with findings from the CLEAR Wisdom randomized

clinical trial. In that study, bempedoic acid added to maximally tolerated statin therapy resulted in a 15.1% reduction in LDL-C at week 12, whereas the placebo group demonstrated a 2.4% increase, resulting in a between-group difference of approximately 17.4 percentage points. In the present study, the corresponding difference was approximately 17.2 percentage points (–18.7% versus –1.5%). The similarity between these findings supports the additional LDL-C-lowering effect of bempedoic acid when used alongside stable statin therapy [7].

A similar pattern was observed for non-HDL-C. In the present study, non-HDL-C decreased by 13.3% in the bempedoic acid group compared with only 1.2% in the control group. The CLEAR Wisdom trial reported a 10.8% reduction in non-HDL-C with bempedoic acid compared with a 2.3% increase with placebo [7]. Furthermore, a secondary analysis of the CLEAR Harmony trial reported a placebo-corrected reduction of approximately 14.3% in non-HDL-C at 12 weeks [13]. The 13.3% reduction observed in the present study therefore falls within the range reported in previous clinical studies. The findings of the present study are also comparable with more recent evidence evaluating bempedoic acid in routine clinical settings. A 12-week pragmatic study from Taiwan reported a median LDL-C reduction of approximately 19% and a non-HDL-C reduction of 13.3% following bempedoic acid treatment, closely corresponding to the 18.7% and 13.3% reductions observed in the present study. These similarities across different study populations and treatment settings suggest a relatively consistent lipid-lowering response following addition of bempedoic acid to background lipid-lowering therapy [14].

Strengths and Limitations

The strengths of this study include its comparative design, evaluation of both LDL-C and non-HDL-C, standardized 12-week follow-up, and assessment of outcomes in a real-world government hospital setting. However, the retrospective design, relatively small sample size, single-centre setting, and short follow-up duration limit generalizability and assessment of long-term efficacy and safety. Potential residual confounding and incomplete documentation of adherence and other lifestyle factors may also have influenced the observed outcomes.

Conclusion

Addition of bempedoic acid 180 mg once daily to stable statin therapy was associated with greater reductions in LDL-C and non-HDL-C over 12 weeks compared with stable statin therapy alone. These findings support the potential role of bempedoic acid as an adjunctive lipid-lowering

therapy in patients with persistent dyslipidemia despite statin treatment. Further prospective, multicentre studies with larger sample sizes and longer follow-up are warranted to confirm these findings and evaluate long-term clinical outcomes and safety.

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