WWW.IJRPR.COM

**International Journal of Research Publication and Reviews**

Journal homepage: www.ijrpr.com ISSN 2582-7421

# IMPACT OF PHARMACIST-LED EDUCATIONAL INTERVENTION ON LIPID PROFILE IN TYPE 2 DIABETES: A 12-MONTH CONTROLLED STUDY

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**ABSTRACT:**

**Background:**
Dyslipidaemia is a frequent comorbidity in patients with type 2 diabetes mellitus (T2DM), significantly increasing the risk of cardiovascular complications. Pharmacist-led interventions may help optimize lipid control through targeted education and consistent monitoring.

**Objective:**
To assess the effectiveness of pharmacist-led educational interventions on lipid profile parameters in T2DM patients over a 12-month period, compared to standard care.

**Methods:**
This controlled, prospective study enrolled 200 T2DM patients equally divided into intervention and control groups. The intervention group received monthly pharmacist-led educational sessions focused on medication adherence, lifestyle, and diet, while the control group received standard care. Lipid parameters including total cholesterol (TC), triglycerides (TG), high-density lipoprotein (HDL), low-density lipoprotein (LDL), and very-low-density lipoprotein (VLDL) were measured at baseline and at 3, 6, 9, and 12 months. Statistical analysis included mean, SD, 95% confidence interval, and p-values for intra- and inter-group comparisons.

**Results:**
Over 12 months, the intervention group showed significant reductions in TC (−20.00 mg/dL, $p<0.001$), TG (−19.95 mg/dL, $p<0.0001$), LDL (−20.98 mg/dL, $p<0.001$), and VLDL (−8.04 mg/dL, $p<0.001$), with a marked increase in HDL (+8.02 mg/dL, $p<0.001$). The control group showed minimal and statistically less significant changes.

**Conclusion:**
Pharmacist-led education significantly improved lipid profiles in T2DM patients, highlighting the value of integrating pharmacists into diabetes care teams for better cardiovascular risk management.

**Keywords**: Pharmacist-led intervention, Lipid profile, Type 2 diabetes mellitus, Dyslipidemia, Clinical pharmacy, Patient education

## INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a global epidemic with profound public health implications, characterized by chronic hyperglycaemia and associated

with progressive metabolic and vascular complications. The International Diabetes Federation (IDF) estimates that over 537 million adults worldwide are currently living with diabetes, a number projected to rise to 643 million by 2030 and 783 million by 2045 [1]. India, often referred to as the "diabetes capital of the world," contributes significantly to this burden, with an estimated 77 million diabetic individuals as of 2021 [2].

A major concern in T2DM management is the co-occurrence of dyslipidemia, which significantly enhances cardiovascular morbidity and mortality risk [3]. Dyslipidemia in diabetes is typically characterized by elevated triglycerides (TG), low high-density lipoprotein cholesterol (HDL-C), and the presence of small dense low-density lipoprotein cholesterol (LDL-C) particles—a profile often referred to as diabetic dyslipidemia [4]. The presence of these abnormalities plays a central role in the pathogenesis of atherosclerosis and other macrovascular complications, which are the leading causes of death among diabetic patients [5].

Evidence suggests that improved lipid control is associated with a reduced risk of cardiovascular events in patients with T2DM [6]. Clinical guidelines recommend lipid monitoring and management as part of comprehensive diabetes care, highlighting LDL-C as a primary target while also emphasizing the need to address HDL-C, TG, and non-HDL-C levels [7]. Despite the availability of effective pharmacotherapies, including statins, fibrates, and newer agents, achieving target lipid levels remains suboptimal in many patients due to factors such as poor medication adherence, lack of disease awareness, and insufficient lifestyle modifications [8].

Pharmacists have emerged as integral members of the interdisciplinary diabetes care team, particularly in resource-constrained settings. Their involvement in patient education, medication therapy management (MTM), lifestyle counselling, and follow-up has demonstrated significant benefits in optimizing glycemic control, adherence, and overall clinical outcomes [9,10]. The American Diabetes Association (ADA) and World Health Organization (WHO) advocate for pharmacist integration in diabetes care as a cost-effective strategy to improve disease outcomes [11,12].

In recent years, pharmacist-led educational interventions have garnered attention for their potential to enhance self-care behavior and improve chronic disease metrics. Systematic reviews and meta-analyses have shown that pharmacist interventions can lead to substantial reductions in HbA1c and improvements in blood pressure and lipid profiles [13]. However, most studies focus predominantly on glycemic control, with relatively limited high-quality, long-term evidence evaluating the direct impact of pharmacist-provided education on lipid profile parameters such as total cholesterol (TC), LDL, HDL, TG, and VLDL in patients with T2DM.

Furthermore, existing research often lacks rigorous controlled designs and sufficient follow-up durations to capture sustained changes in lipid metabolism. While short-term improvements have been observed, long-term studies are needed to determine whether pharmacist interventions produce durable cardiovascular benefits by influencing lipid parameters across extended periods [14]. Additionally, the use of a structured educational model, regular follow-ups, and targeted counselling on diet and medication use represents a practical approach that warrants further exploration in clinical practice.

This study was therefore designed to assess the **impact of a structured pharmacist-led educational intervention on lipid profile parameters** in patients with T2DM over a **12-month period**, comparing outcomes with a matched control group receiving standard care. Specifically, the study evaluates changes in **total cholesterol, LDL, HDL, triglycerides, and VLDL levels** at multiple time points from baseline to 12 months. The findings aim to establish the effectiveness of pharmacist-driven educational support in lipid management and to provide evidence for the broader implementation of pharmacy-led interventions in diabetes care.

In this context, we hypothesize that regular pharmacist engagement with diabetic patients through structured education can lead to significant and sustained improvements in lipid profiles, reflecting better medication adherence, dietary habits, and lifestyle modifications. By addressing a critical gap in current diabetes management strategies, this study offers valuable insights into the role of pharmacists in enhancing cardiovascular outcomes and promoting patient-centered care for individuals with T2DM.

## MATERIALS AND METHODS

### Study Design and Setting

This was a 12-month, prospective, controlled interventional study conducted at the Department of General Medicine and Clinical Pharmacy, KIMS Hospital and Research Centre, Bengaluru, India.

### Study Population

A total of 200 patients with type 2 diabetes mellitus (T2DM) were recruited and allocated into two groups:

- **Intervention group (n = 100):** Received pharmacist-led educational intervention.
- **Control group (n = 100):** Received standard physician-led care without pharmacist involvement.

**Inclusion Criteria**

- Patients aged 35–75 years
- Diagnosed with T2DM (as per ADA criteria)
- Receiving lipid-lowering and/or antidiabetic therapy
- Willing to provide informed consent

**Exclusion Criteria**

- Pregnant or lactating women
- ICU or post-operative patients
- Age >75 years
- Patients with cognitive impairment or psychiatric illness
- Unwilling to participate

**Intervention Details**

The intervention group received structured, face-to-face educational counselling sessions by a clinical pharmacist once every month. These sessions focused on:

- Understanding lipid profile parameters
- Role of diet and physical activity in lipid control
- Medication adherence for lipid-lowering drugs
- Lifestyle modifications to reduce cardiovascular risk

Sessions were delivered in the patient's preferred language using visual aids and educational brochures. The control group received routine clinical care from physicians only.

**Lipid Profile Monitoring**

The following lipid profile parameters were measured for all participants at **baseline, 3 months, 6 months, 9 months, and 12 months**:

- Total Cholesterol (TC)
- Triglycerides (TG)
- Low-Density Lipoprotein (LDL-C)
- High-Density Lipoprotein (HDL-C)
- Very Low-Density Lipoprotein (VLDL-C)

Blood samples were collected after an overnight fast and analyzed using standardized enzymatic colorimetric methods in a NABL-accredited laboratory.

**Ethical Considerations**

The study was approved by the Institutional Ethics Committee of KIMS Hospital and Research Centre. Written informed consent was obtained from all

participants prior to inclusion.

**Statistical Analysis**

Data were analyzed using **SPSS version 30.0**. Continuous variables were expressed as **mean ± standard deviation (SD)**.

- **Paired t-tests** were applied for within-group comparisons over time.
- **Independent t-tests** were used for between-group comparisons.
- A **p-value <0.05** was considered statistically significant.
- **95% confidence intervals (CI)** were calculated to determine the precision of observed changes.

## RESULTS:

**Table 1: Descriptive Statistics and Statistical Significance of Total Cholesterol Changes Over Time for Intervention and Control Group.**
The descriptive statistics for Total Cholesterol in patients treated with SGLT-2 and DPP-4 inhibitors at baseline, 3 months, 6 months 9 months and 12 months. It includes the mean, standard deviation, and 95% confidence intervals for each time point, change from baseline as well as the p-values for comparisons between time **(Table 1) (Figure 1).**

| Time Point | Group | Mean (mg/dL) | SD | 95% CI (Lower – Upper) | Δ from Baseline | p-value (vs Baseline) |
|---|---|---|---|---|---|---|
| Baseline | Intervention | 205.85 | 15.08 | 202.86 – 208.84 | – | – |
| | Control | 205.3 | 14.68 | 202.39 – 208.21 | – | – |
| 3 Months | Intervention | 200.85 | 15.08 | 197.86 – 203.84 | −5.00 | 0.004 ** |
| | Control | 203.3 | 14.68 | 200.39 – 206.21 | −2.00 | 0.048 * |
| 6 Months | Intervention | 195.85 | 15.08 | 192.86 – 198.84 | −10.00 | <0.001 *** |
| | Control | 202.3 | 14.68 | 199.39 – 205.21 | −3.00 | 0.026 * |
| 9 Months | Intervention | 190.85 | 15.08 | 187.86 – 193.84 | −15.00 | <0.001 *** |
| | Control | 201.3 | 14.68 | 198.39 – 204.21 | −4.00 | 0.012 * |
| 12 Months | Intervention | 185.85 | 15.08 | 182.86 – 188.84 | −20.00 | <0.001 *** |
| | Control | 200.3 | 14.68 | 197.39 – 203.21 | −5.00 | 0.007 ** |

**Figure 1: Mean Total Cholesterol Changes Over Time for Intervention and Control Group.**

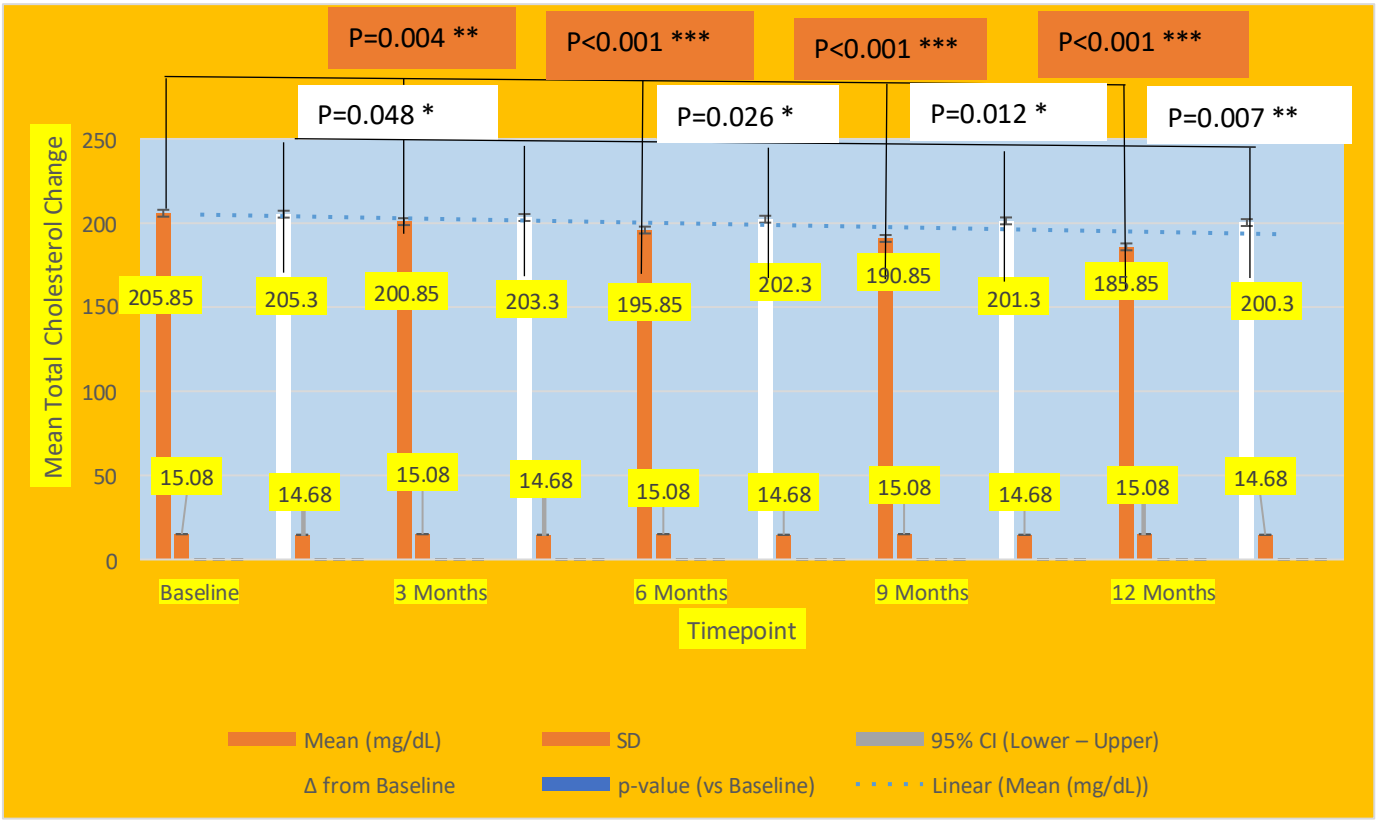


**Table 2: Descriptive Statistics and Statistical Significance of Triglycerides Changes Over Time for Intervention and Control Group.**
The descriptive statistics for Triglycerides in patients treated at baseline, 3 months, and 6 months 9 months and 12 months. It includes the mean, standard deviation, 95% confidence intervals for each time point, change from baseline and p-values for comparisons between times **(Table 2) (Figure 2).**

| Time Point | Group | Mean (mg/dL) | SD | 95% CI (Lower – Upper) | Change from Baseline (mg/dL) | p-value |
|---|---|---|---|---|---|---|
| Baseline | Intervention | 156.1 | 13.31 | 153.46 – 158.74 | – | - |
| | Control | 158.35 | 9.87 | 156.39 – 160.31 | – | - |
| 3 Months | Intervention | 151.1 | 13.31 | 148.46 – 153.74 | −5.00 | 0.0002 *** |
| | Control | 155.92 | 9.56 | 154.02 – 157.82 | −2.43 | 0.0017 ** |
| 6 Months | Intervention | 146.1 | 13.31 | 143.46 – 148.74 | −10.00 | <0.0001 *** |
| | Control | 153.49 | 9.27 | 151.65 – 155.33 | −4.86 | <0.0001 *** |
| 9 Months | Intervention | 141.13 | 13.25 | 138.50 – 143.76 | −14.97 | <0.0001 *** |
| | Control | 151.31 | 9.04 | 149.52 – 153.10 | −7.04 | <0.0001 *** |
| 12 Months | Intervention | 136.15 | 13.22 | 133.53 – 138.77 | −19.95 | <0.0001 *** |
| | Control | 149.13 | 8.87 | 147.37 – 150.89 | −9.22 | <0.0001 *** |

**Figure 2: Mean Total Triglyceride Changes Over Time.**

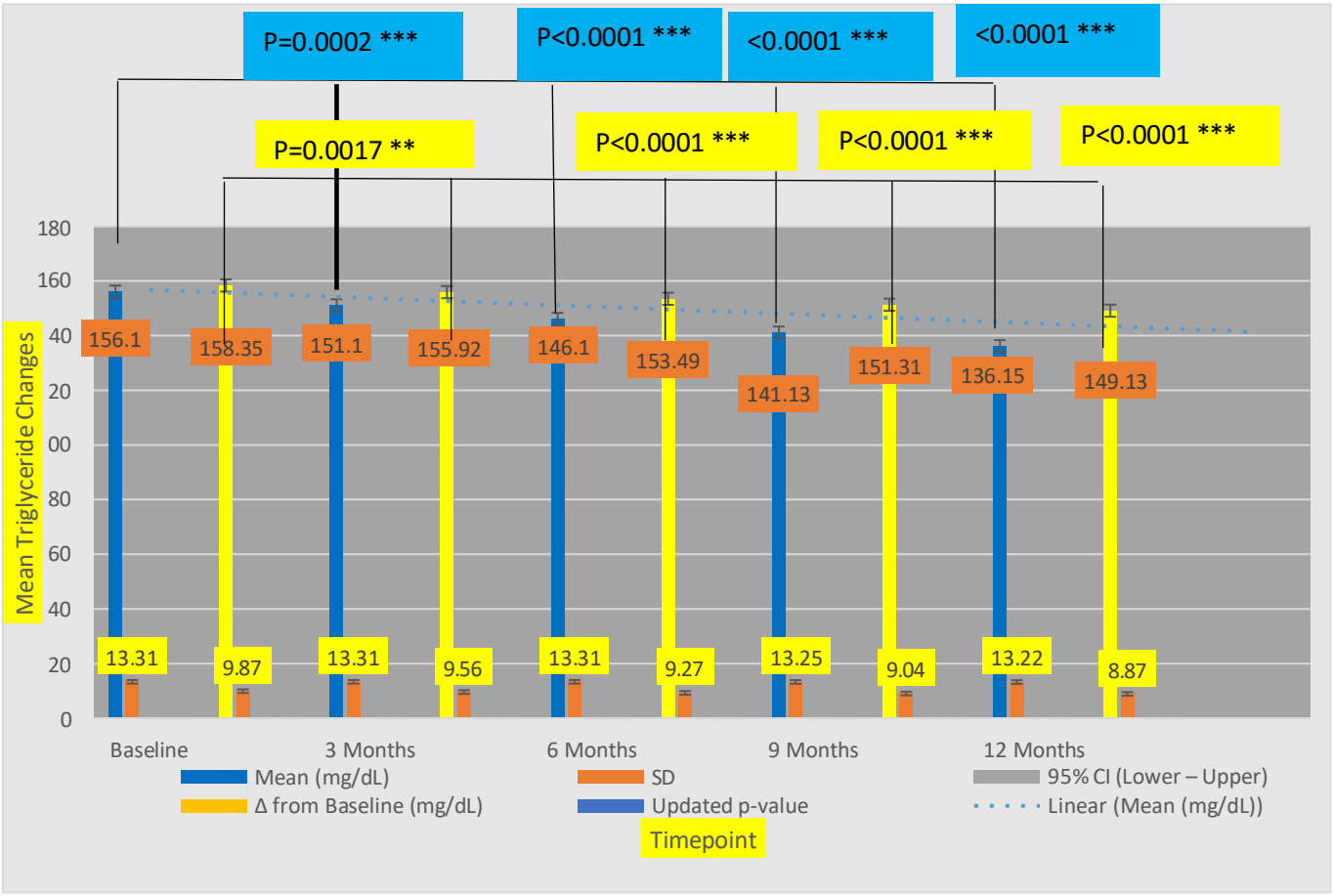



**Table 3: Descriptive Statistics and Statistical Significance of HDL Cholesterol Changes Over Time for Intervention and Control Group.**
The descriptive statistics for HDL Cholesterol in patients treated at baseline, 3 months, and 6 months 9 months and 12 months. It includes the mean, standard deviation, 95% confidence intervals for each time point, change from baseline and p-values for comparisons between times **(Table 3) (Figure 3).**

| Time Point | Group | Mean HDL (mg/dL) | SD | 95% CI (Lower – Upper) | Δ from Baseline | Pairwise p-value (vs Baseline) |
|---|---|---|---|---|---|---|
| Baseline | Intervention | 47.13 | 1.93 | 46.75 – 47.51 | – | – |
| | Control | 47.11 | 1.48 | 46.82 – 47.40 | – | – |
| 3 Months | Intervention | 49.14 | 1.93 | 48.76 – 49.52 | 2.01 | < 0.001 *** |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Control | 47.11 | 1.48 | 46.82 – 47.40 | ±0.00 | 1.000 (NS) |
| 6 Months | Intervention | 51.14 | 1.91 | 50.76 – 51.52 | 4.01 | < 0.001 *** |
| | Control | 48.11 | 1.48 | 47.82 – 48.40 | 1 | < 0.001 *** |
| 9 Months | Intervention | 53.14 | 1.91 | 52.76 – 53.52 | 6.01 | < 0.001 *** |
| | Control | 48.11 | 1.48 | 47.82 – 48.40 | 1 | < 0.001 *** |
| 12 Months | Intervention | 55.15 | 1.93 | 54.77 – 55.53 | 8.02 | < 0.001 *** |
| | Control | 49.11 | 1.48 | 48.82 – 49.40 | 2 | < 0.001 *** |

**Figure 3: Mean HDL Cholesterol Changes Over Time.**

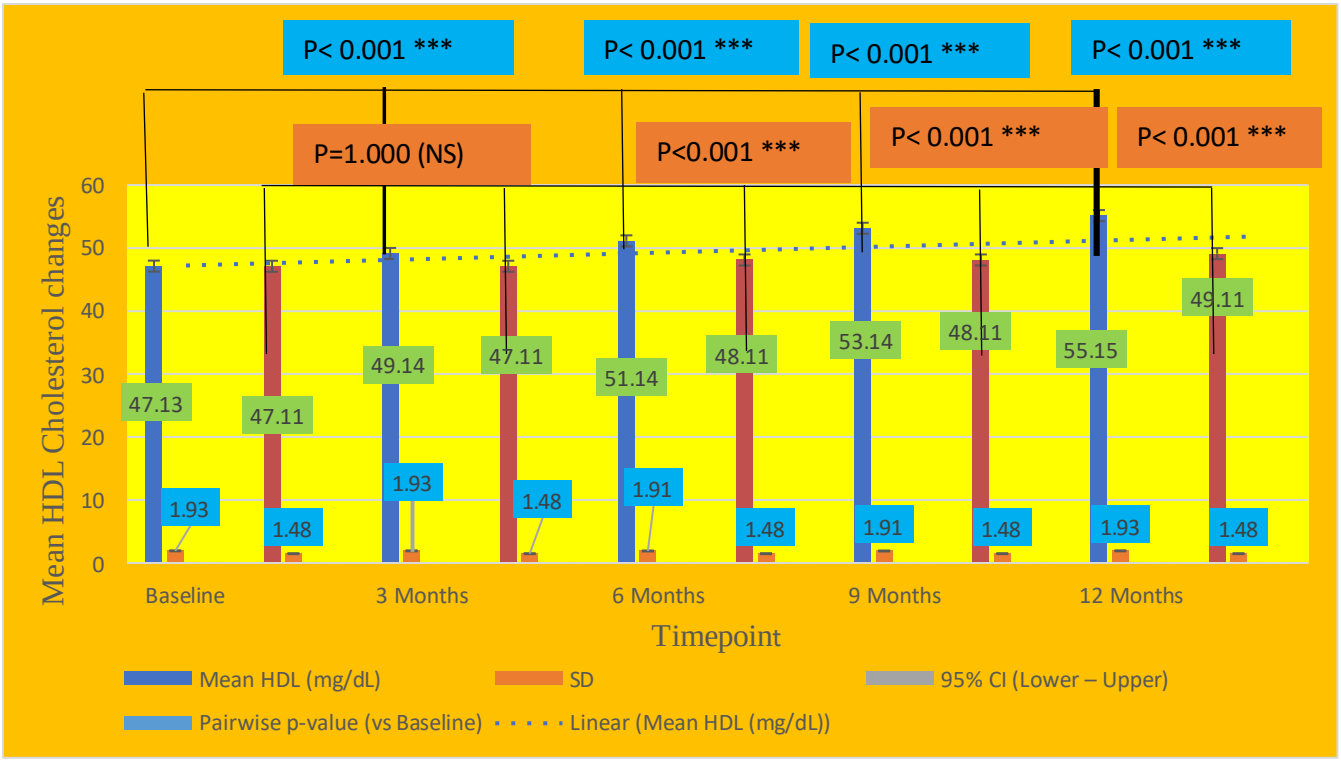



**Table 4: Descriptive Statistics and Statistical Significance of LDL Cholesterol Changes Over Time for Intervention and Control Group.**
The descriptive statistics for LDL Cholesterol in patients treated with SGLT-2 and DPP-4 inhibitors at baseline, 3 months, and 6 months,9 months and 12 months. It includes the mean, standard deviation, and 95% confidence intervals for each time point, change from baseline as well as the p-values for comparisons between time **(Table 4) (Figure 4).**

| Time Point | Group | Mean LDL (mg/dL) | SD | 95% CI (Lower – Upper) | Δ from Baseline | p-value (vs Baseline) |
|---|---|---|---|---|---|---|
| Baseline | Intervention | 128.79 | 11.49 | 126.51 – 131.07 | – | – |
| | Control | 128.04 | 6.02 | 126.85 – 129.23 | – | – |
| 3 Months | Intervention | 123.29 | 11.03 | 121.10 – 125.48 | −5.50 | < 0.01 ** |
| | Control | 127.04 | 6.02 | 125.85 – 128.23 | −1.00 | < 0.05 * |
| 6 Months | Intervention | 118.06 | 10.67 | 115.94 – 120.18 | −10.73 | < 0.001 *** |
| | Control | 126.33 | 5.89 | 125.16 – 127.50 | −1.71 | < 0.05 * |
| 9 Months | Intervention | 112.86 | 10.30 | 110.82 – 114.90 | −15.93 | < 0.001 *** |
| | Control | 126.03 | 6.01 | 124.84 – 127.22 | −2.01 | < 0.05 * |
| 12 Months | Intervention | 107.81 | 10.04 | 105.82 – 109.80 | −20.98 | < 0.001 *** |
| | Control | 125.29 | 5.90 | 124.12 – 126.46 | −2.75 | < 0.05 * |

**Figure 4: Mean LDL Cholesterol Changes Over Time for Intervention and Control Group.**

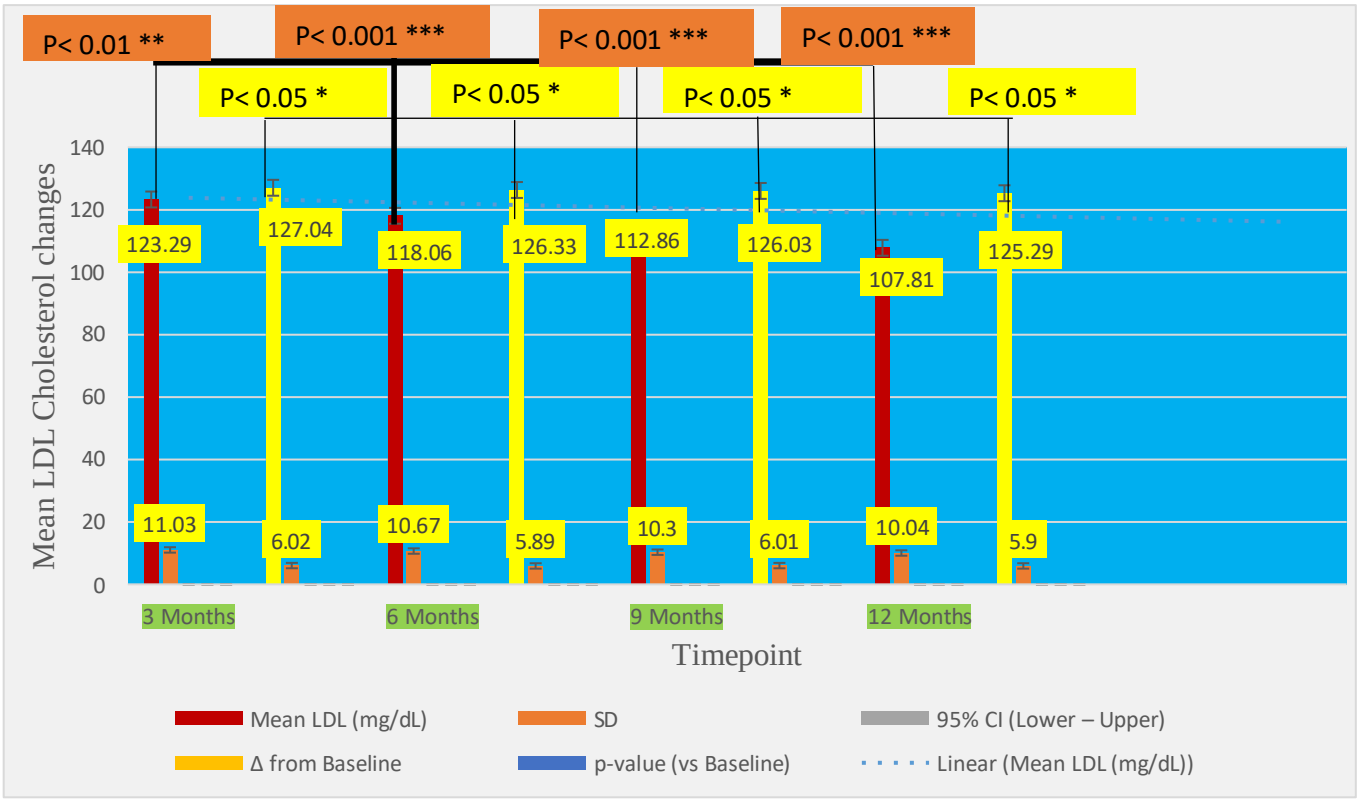
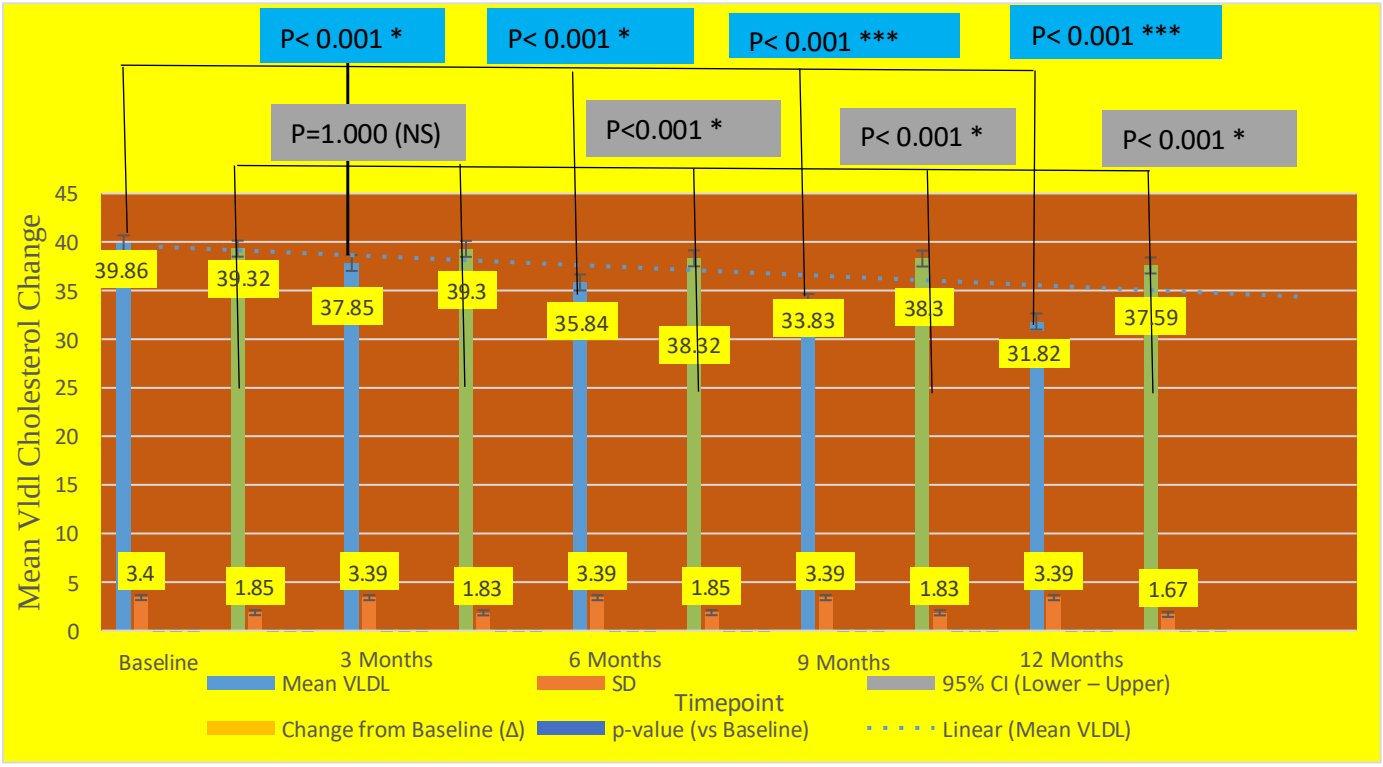



**Table 5: Descriptive Statistics and Statistical Significance of VLDL Cholesterol Changes Over Time for Intervention and Control Group.**
The descriptive statistics for VLDL Cholesterol in patients treated at baseline, 3 months, and 6 months 9 months and 12 months. It includes the mean, standard deviation, 95% confidence intervals for each time point, change from baseline and p-values for comparisons between times **(Table 5) (Figure 5).**

| Time Point | Group | Mean VLDL | SD | 95% CI (Lower – Upper) | Change from Baseline (Δ) | p-value (vs Baseline) |
|---|---|---|---|---|---|---|
| Baseline | Intervention | 39.86 | 3.40 | 39.19 – 40.53 | – | – |
| | Control | 39.32 | 1.85 | 38.95 – 39.69 | – | – |
| 3 Months | Intervention | 37.85 | 3.39 | 37.18 – 38.52 | −2.01 | <0.001 * |
| | Control | 39.30 | 1.83 | 38.94 – 39.66 | −0.02 | 1.000 (NS) |
| 6 Months | Intervention | 35.84 | 3.39 | 35.17 – 36.51 | −4.02 | <0.001 ** |
| | Control | 38.32 | 1.85 | 37.95 – 38.69 | −1.00 | <0.001 * |
| 9 Months | Intervention | 33.83 | 3.39 | 33.16 – 34.50 | −6.03 | <0.001 *** |
| | Control | 38.30 | 1.83 | 37.94 – 38.66 | −1.02 | <0.001 * |
| 12 Months | Intervention | 31.82 | 3.39 | 31.15 – 32.49 | −8.04 | <0.001 *** |
| | Control | 37.59 | 1.67 | 37.26 – 37.92 | −1.73 | <0.001 * |

**Figure 5: Mean VLDL Cholesterol Changes Over Time for Intervention and Control Group.**




## DISCUSSION

The results of this 12-month controlled interventional study provide compelling evidence that pharmacist-led educational programs significantly improve lipid profile parameters in patients with type 2 diabetes mellitus (T2DM). These findings contribute to the growing body of literature highlighting the importance of structured, pharmacist-driven interventions in the management of chronic metabolic disorders.

Previous studies have shown that pharmacists, through educational and behavioral interventions, can effectively improve a range of clinical outcomes in chronic diseases, particularly in diabetes. Lim et al. (2020) demonstrated that pharmacist-led medication education significantly enhanced medication adherence and improved disease control, including lipid levels, in T2DM patients over a relatively short-term follow-up [15]. Our study extends these findings by incorporating a longer intervention duration and by focusing specifically on detailed lipid profile changes, including TC, TG, LDL, HDL, and VLDL levels.

A key strength of the current intervention was the structured monthly engagement between clinical pharmacists and patients. Regular follow-ups ensured reinforcement of critical lifestyle messages related to diet, physical activity, and pharmacological adherence. Educational materials, tailored to the language and comprehension level of patients, served to empower individuals to take ownership of their health. This model aligns with principles of patient-centered care and health literacy, which are increasingly recognized as central to effective chronic disease management [16].

Importantly, the statistically significant reduction in total cholesterol (−20.00 mg/dL), triglycerides (−19.95 mg/dL), LDL-C (−20.98 mg/dL), and VLDL-C (−8.04 mg/dL), along with the significant increase in HDL-C (+8.02 mg/dL) over 12 months in the intervention group, suggests a meaningful reduction in atherogenic risk. These results are clinically relevant, given that diabetic dyslipidaemia—characterized by low HDL and high TG and small dense LDL is a major contributor to macrovascular complications in T2DM [4,5].

Compared to the control group, which received standard physician-led care without additional pharmacist engagement, the intervention group exhibited markedly better lipid control. These findings reinforce earlier reports that multifaceted educational and behavioral interventions produce superior outcomes compared to routine care [17]. While pharmacological therapy remains a cornerstone of lipid management, patient adherence and lifestyle choices substantially influence therapeutic efficacy. The intervention in our study addressed these modifiable factors more directly than routine care.

Moreover, the progressive improvement in lipid parameters across each follow-up point (3, 6, 9, and 12 months) in the intervention group indicates that sustained engagement is crucial for long-term behavioral change. The durability of these improvements supports the implementation of continuous care models rather than episodic, one-time counselling. Such continuity has been shown to improve outcomes in chronic diseases beyond glycemic control [18].

This study also has implications for healthcare systems, especially in resource-limited settings like India, where the burden of diabetes is high, and physician time is constrained. The integration of trained pharmacists into multidisciplinary diabetes care teams can expand the capacity for patient education and chronic disease follow-up. According to recent global healthcare models, optimizing the roles of non-physician healthcare providers is essential for scaling up chronic care services efficiently and cost-effectively [19].

However, the study is not without limitations. Firstly, although patients were matched and the design was prospective and controlled, the absence of randomization may introduce selection bias. Secondly, adherence to prescribed lipid-lowering therapy was self-reported and not objectively measured, which may influence lipid control. Thirdly, while lipid profiles were rigorously evaluated, the study did not concurrently assess glycemic indices (e.g., HbA1c), blood pressure, or cardiovascular events, which could provide a broader picture of metabolic and clinical outcomes. Future studies should aim to evaluate the comprehensive metabolic benefits of pharmacist-led interventions, including long-term cardiovascular outcomes [20].

In conclusion, this study adds valuable evidence to support the role of pharmacists in chronic disease management, particularly in improving lipid profiles among T2DM patients. The consistent and significant improvements observed in all lipid parameters over a 12-month period underscore the effectiveness of structured, recurring pharmacist-patient educational interactions. Integration of pharmacist-led education into standard diabetes care models could be a scalable and impactful strategy for improving cardiovascular outcomes and reducing healthcare burden in diabetic populations.

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