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Evaluation of Clinical Pharmacist Led Guidance on Treatment Outcomes, Treatment Adherence & Quality of Life Among T2DM Patients Attending Endocrinology Out Patient Department in a Tertiary Care Hospital

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ABSTRACT: Clinical pharmacist-led guidance was evaluated in a 6-month prospective observational study of 90 T2DM patients at a tertiary care hospital. Participants were distributed into test (Group A; n = 45) and control (Group B; n = 45) groups. Group A received structured clinical pharmacist counselling on medication regimens, adherence, lifestyle modifications, and ADR monitoring, whereas Group B received standard care. Outcomes measured at baseline and 2 months included glycaemic profiles, lipid profile, medication adherence (MARS-10), and quality of life (WHOQOL-BREF). Group A exhibited significant improvements in FBS, PPBS, medication adherence, and quality of life physical and psychological domains. HbA1c and lipid profile showed favourable but non-significant trends. No major ADRs were reported. These findings support integration of pharmacist-led guidance and care in chronic disease management.

KEYWORDS: Clinical Pharmacist, Medication Adherence, Quality of Life, MARS-10, Type 2 Diabetes Mellitus, WHOQOL-BREF.

INTRODUCTION

T2DM is a growing public health burden in India, with over 75 million affected, particularly in urban and semi-urban regions due to lifestyle factors[1]. India has one of the highest diabetes cases worldwide along with an estimated 75 million adults living with diabetes in 2021 is a major challenge to the healthcare systems[2]. The rapid increase in the diabetes cases is due to urbanization, sedentary lifestyles, poor diet and genetic factors[2]. It is the leading cause of morbidity and mortality putting immense pressure on the healthcare systems[2]. Eastern India including the states of West Bengal, Odisha, Bihar, Jharkhand experiences a higher prevalence of diabetes like 6.81% compared to the national average[3]. This region faces limited healthcare infrastructure, lack of awareness and socio-economic barriers that potentiate the impact of diabetes[2]. Chronic disease management hinges not only on medication but also on patient education, adherence, and lifestyle intervention[4][5][6]. Clinical pharmacists offer medication optimization and patient-centred care, bridging critical gaps in traditional care models[7][8][9]. This study investigates the impact of pharmacist-led interventions on glycaemic control, adherence, and QoL in T2DM patients at a tertiary care hospital.

METHODS

Study Design & Setting:

Prospective observational interventional study at the Endocrine OPD of School of Tropical Medicine, Kolkata, over 6 months.

Study Population:

Inclusion criteria: Patients with T2DM on ≥2 oral agents for ≥3 months; consented to participate.
Exclusion criteria: Unwilling to participate in the study.

Study Plan:

All the participants were informed about the study prior to the initiation and were allowed to sign the Informed Consent Document for receiving their consent. Ninety participants were distributed into two groups equally to Group A (structured clinical pharmacist counselling) or Group B (standard care). Counselling covered disease education, medication adherence, lifestyle modifications, and ADR monitoring.

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Study Outcomes & Assessment:
Measured at baseline and 2 months:

- Glycaemic outcomes: FBS, PPBS, HbA1c
- Lipid outcomes: Triglycerides, LDL, HDL, Total Cholesterol
- Medication Adherence: MARS-10 scale
- Quality of Life: WHOQOL-BREF (Physical, Psychological, Social Relationships, Environmental domains)
- Safety: Recorded ADRs

Statistical Analysis:
Data analysis was done using SPSS v27 and Excel. Paired/unpaired t-tests and chi-square tests; significance threshold $p < 0.05$.

RESULTS

Demographics and Baseline Characteristics:

Out of 90 participants 74 participants completed the study (Group A = 40; Group B = 34). Mean age: Group A 55 ± 10 yrs; Group B 51 ± 11 yrs. Gender distribution and duration of diabetes were comparable.

Comorbidities and Complications:
Hypertension (67.5%), hypothyroidism, dyspepsia common; neuropathy/nephropathy rates similar across groups.

Glycaemic Parameters:
Group A showed significant reductions:

- FBS: 136.6 → 101.3 mg/dL ($p = 0.0003$)
- PPBS: 195.7 → 141.9 mg/dL ($p = 0.002$)

HbA1c decreased from 7.33% to 6.77%, not statistically significant ($p = 0.157$).

Lipid Profile:
Group A demonstrated favourable but non-significant improvements in triglycerides, LDL and HDL but showed significant improvement in total cholesterol.

- TG: 131 → 109.46 mg/dL ($p = 0.073$)
- LDL: 81 → 63 mg/dL ($p = 0.086$)
- HDL: 40 → 43.33 mg/dL ($p = 0.515$)
- TC: 149 → 110.38 mg/dL ($p = 0.0001$)

Medication Adherence:
High adherence rates rose from 80% to 97.5% in Group A (versus 85.3% → 88.2% in Group B; $p = 0.013$).

Quality of Life:
Group A showed significant improvements in WHOQOL-BREF physical (37.8 → 58.3; $p = 0.0001$) and psychological (41.5 → 50.7; $p = 0.02$) domains. Social (43.28 → 49.2; $p = 0.07$) and environmental (34.03 → 37.73; $p = 0.665$) improvements were non-significant.

Safety:
No major ADRs reported in either group.

DISCUSSION

This study demonstrates that even short-term pharmacist-led interventions can significantly improve glycaemic control, medication adherence, and quality of life among T2DM patients. The reduction in FBS and PPBS was statistically significant in the intervention group, which underscores the value of continuous education and lifestyle monitoring by a clinical pharmacist. Although HbA1c levels showed improvement, the change was not statistically significant, likely due to the short two-month follow-up period, as HbA1c reflects glycaemic control over approximately 90 days[10].

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Similarly, lipid profile improvements, especially the significant drop in total cholesterol, suggest early positive metabolic changes that may become more pronounced over longer durations. The increase in medication adherence seen in Group A aligns with previous findings indicating that pharmacist counselling enhances understanding and engagement in treatment, which is critical for chronic disease management[11].

Improvements in the WHOQOL-BREF physical and psychological domains reflect the broader impact of pharmacist support on patient well-being beyond biochemical control. These findings support the integration of clinical pharmacists into chronic disease management teams, especially in resource-limited settings where physician-patient interaction time is constrained[12].

Future studies should focus on longer-term, multi-centre trials that incorporate a broader patient base to validate and generalize these findings. Institutionalizing pharmacist-led care as part of routine primary diabetes management may lead to sustained improvements in treatment outcomes, quality of life, and healthcare system efficiency[13].

Future Directions:

Larger multi-centred trials with ≥6 months follow-up. Institutionalization of pharmacist-led services within primary diabetes care. Continued use of validated tools (MARS-10, WHOQOL-BREF) for longitudinal monitoring.

CONCLUSION

Clinical pharmacist–led guidance significantly improved Fasting blood sugar (FBS) and Post-prandial blood sugar (PPBS) levels, Treatment Adherence, and several Quality-of-Life domains in T2DM patients. Though HbA1c and lipid improvements were not uniformly significant within the short timeframe, consistent positive trends were observed. These results highlight the critical role of pharmacists in chronic disease management and warrant expanded implementation in routine diabetes care.

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It's a fact that every mission needs a spirit of hard work and dedication but it needs to be put on the right path to meet its destination and here the credits go to **Dr. K. RAVI SHANKAR, M. Pharm., PhD, Principal,** Aditya College of Pharmacy, under whose constant supervision, meticulous guidance this work has been carried out in completion. With a deep sense of gratitude for his continuous encouragement, timely advice, cooperation, kind suggestion and providing the best facilities during this work.

Thank you, sir, to show me the way to lift my spirits to believe in me and inspiring me.

FOOT NOTES

Declaration of Patient Consent:

The authors confirm that informed consent has been duly obtained from the patient through a signed consent form. The patient has agreed to the publication of their clinical details and understands that while their name and initials will not be disclosed, efforts will be made to ensure their anonymity.

Financial Support & Sponsorship: None.

Conflicts of Interest: The authors declare no conflicts of interest.

Ethical Approval:

This prospective observational study required Clinical Research Ethics Committee approval (approval number: 2024 AS 104). Informed consent for publication was obtained from the patient and all the identifying information has been anonymized.

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Abbreviations:
T2DM: Type 2 Diabetes Mellitus, **TA:** Treatment Adherence, **TO:** Treatment Outcomes, **QoL:** Quality of Life, **MARS-10:** Medication Adherence Rating Scale, **WHOQOL-BREF:** World Health Organisation Quality of Life – BREF Questionnaire, **FBS:** Fasting Blood Sugar, **PPBS:** Post – Prandial Blood Sugar, **HbA1c:** Glycosylated Haemoglobin, **TG:** Triglycerides, **LDL:** Low Density Lipoprotein, **HDL:** High Density Lipoprotein, **TC:** Total Cholesterol

Summary:
This study was intended to evaluate the Clinical Pharmacist – led Guidance on Treatment Outcomes, Treatment Adherence and Quality of Life among Type 2 Diabetic patients attending the Endocrine OPD in a Tertiary Care Hospital.

Author Contribution:
Samrat Dutta: Study Design, Data collection, manuscript drafting, and coordination
Dr. K. Ravi Shankar: Review, interpretation, refinement and overall supervision
All authors reviewed and approved the final version of the manuscript.

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Tables & Figures:

Table 1: FBS distribution of Study Population			
	Group A	Group B	P value
Baseline	136.61 ± 55.65	152.9 ± 79.94	0.339
1st Month	120.23 ± 20.7	135.77 ± 53.2	
2nd Month	101.36 ± 13.36	140.03 ± 57.83	
Intragroup P Value (Baseline Vs 2nd Month)	0.0003	0.464	

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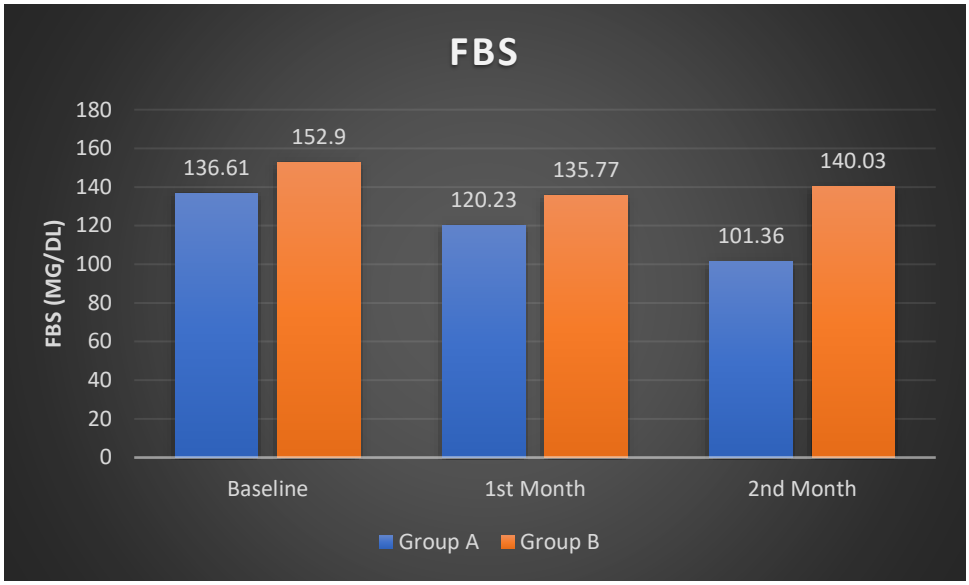

Figure 1: FBS distribution of Study Population

Table 2: PPBS distribution of Study Population			
	Group A	Group B	P value
Baseline	195.78 ± 76.02	244.25 ± 125.18	0.084
1st Month	165.5 ± 52.74	205.15 ± 87.18	
2nd Month	141.92 ± 20.06	188.3 ± 85.78	
Intragroup P Value (Baseline Vs 2nd Month)	0.002	0.521	

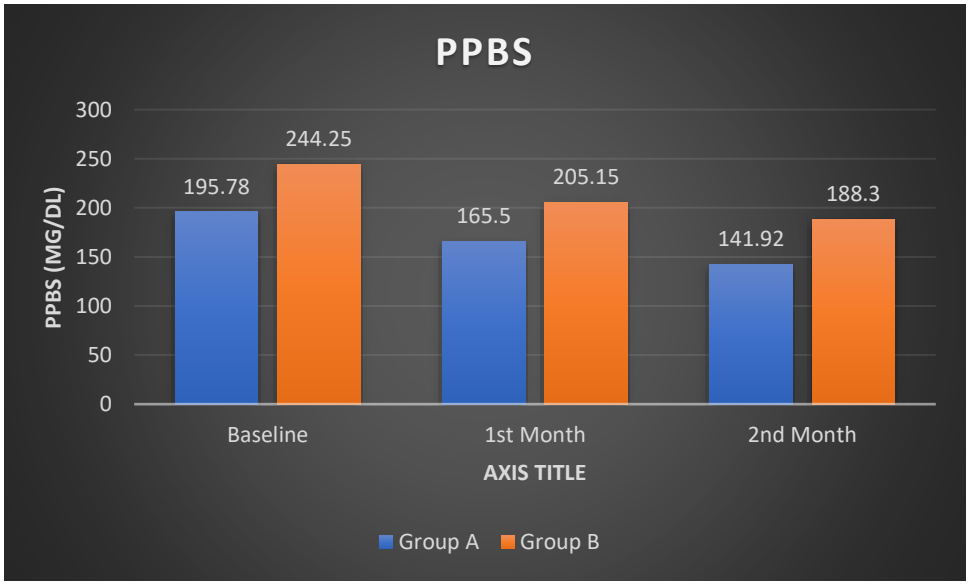

Figure 2: PPBS distribution of Study Population

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Table 3: TC distribution of Study Population			
	Group A	Group B	P value
Baseline	149 ± 9.0	140 ± 9.0	0.553
1st Month	146 ± 35.05	137.33 ± 21.38	
2nd Month	110.38 ± 5.77	135.6 ± 12.13	
Intragroup P Value (Baseline Vs 2nd Month)	0.0001	0.711	

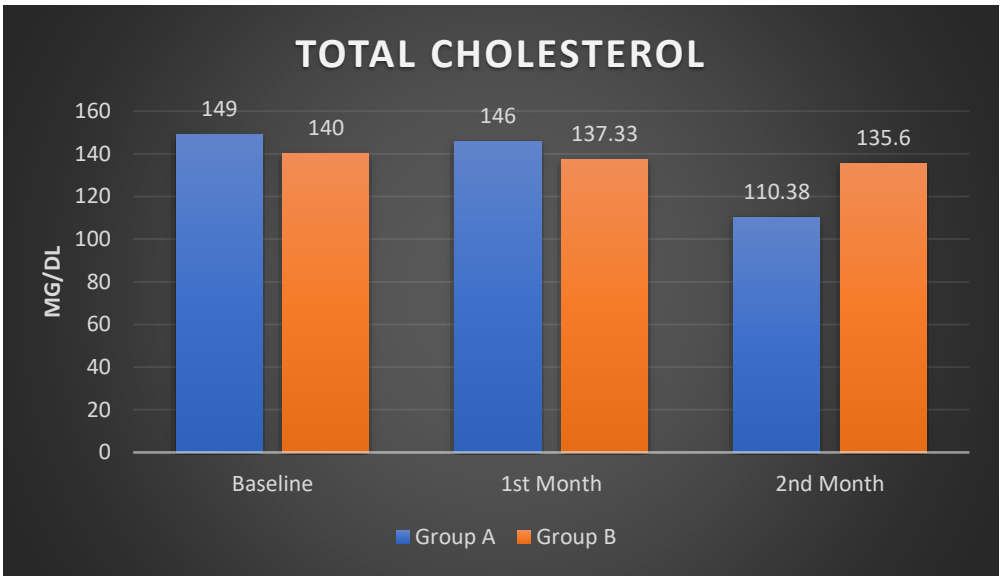

Figure 3: TC distribution of Study Population

Table 4: Treatment Adherence distribution of Study Population				
		Group A	Group B	P Value
Baseline	Low Adherence	8 (20%)	5 (14.71%)	0.551
	High Adherence	32 (80%)	29 (85.29%)	
1st Month	Low Adherence	6 (15%)	5 (14.71%)	
	High Adherence	34 (85%)	29 (85.29%)	
2nd Month	Low Adherence	1 (2.5%)	4 (11.76%)	
	High Adherence	39 (97.5%)	30 (88.24%)	
Intragroup P value (Baseline Vs 2nd Month)		0.013	0.72	

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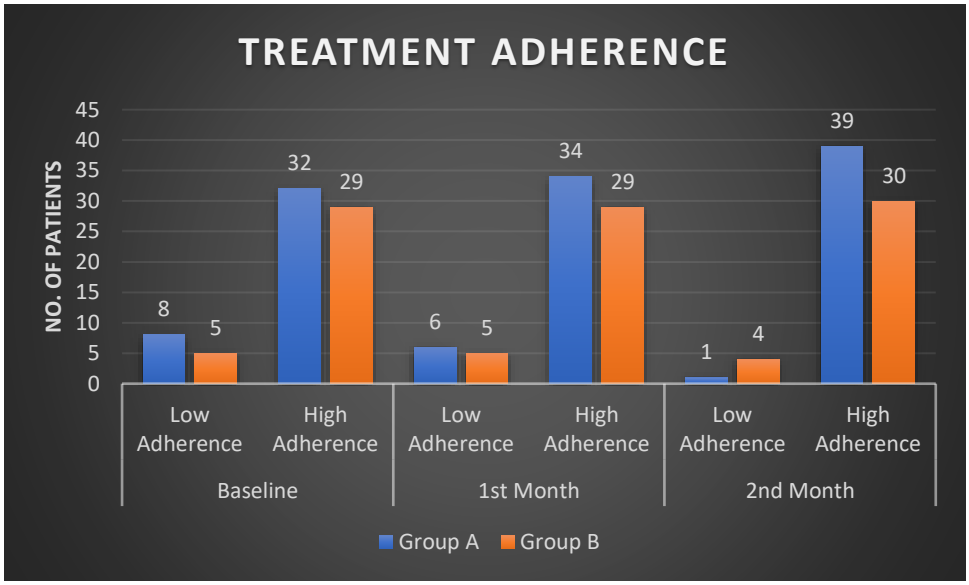

Figure 4: Treatment Adherence distribution of Study Population

Table 5: Domain 1 score distribution of Study Population			
	Group A	Group B	P value
Baseline	37.825 ± 24.28	42.65 ± 18.72	0.355
1st Month	50.15 ± 22.3	44.62 ± 16.81	
2nd Month	58.3 ± 10.68	45.56 ± 15.81	
Intragroup P Value (Baseline Vs 2nd Month)	0.0001	0.497	

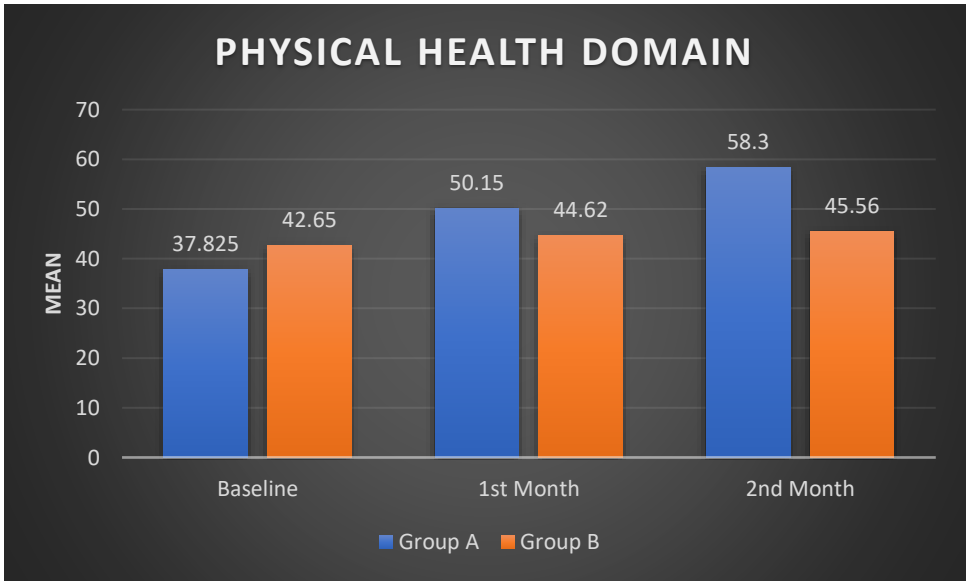

Figure 5: Domain 1 score distribution of Study Population

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Table 6: Domain 2 score distribution of Study Population			
	Group A	Group B	P value
Baseline	41.5 ± 19.34	44.06 ± 15.43	0.542
1st Month	48.2 ± 15.78	45.44 ± 13.81	
2nd Month	50.7 ± 14.51	46.62 ± 12.62	
Intragroup P Value (Baseline Vs 2nd Month)	0.02	0.464	

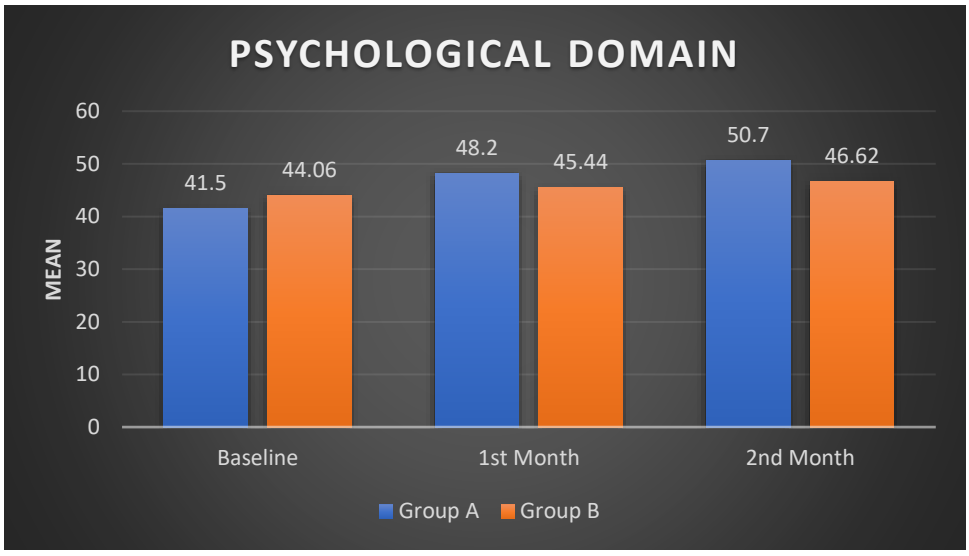

Figure 6: Domain 2 score distribution of Study Population

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