International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Effect of Structured Patient Education on Diabetes Control: A Controlled Trial Approach

Katravath Hari Krishna Naik[1], Gudipati Lokesh[2], Kuruba Kavya[3], Alluri Akshaya[4]

[1,2,3,4] Department of Pharmacy Practice, Santhiram College of Pharmacy. Nandyal-518112. Andra Pradesh-INDIA.

Abstract

Background: Diabetes mellitus is a worldwide health problem with rising morbidity and mortality. Even with improved treatment, most patients are unable to gain optimal glycemic control because of nonadherence, inadequate self-care, and insufficient disease awareness. Organized patient education programs can enhance the management of diabetes by raising awareness, promoting lifestyle changes, and improving treatment adherence.

Objectives: The present research assesses the effect of structured patient education on glycemic control, medication adherence, and knowledge in patients with type 2 diabetes mellitus when compared to standard care.

Methodology: A prospective, randomized controlled trial was carried out at Santhiram Medical College and General Hospital on 48 type 2 diabetes mellitus patients. Participants were assigned to a routine treatment group or routine treatment plus structured patient education. Both the groups were stratified according to glycemic control levels (mild, moderate, severe). The program of structured education comprised disease awareness, dietary advice, physical activity advice, and support for medication adherence. The patients were followed up at an interval of 10 days for three months. Outcome measures were glycated haemoglobin (HbA1c), random blood glucose (RBS), medication adherence (Morisky Medication Adherence Scale), and patient knowledge scores. Statistical analyses comprised paired t-tests, chi-square tests, and ANOVA.

Results: The intervention group had significant changes in HbA1c, RBS, medication adherence, and patient knowledge. Hospital visits reduced, and quality of life was enhanced.

Discussion: Organized patient education improves diabetes control, self-management, and compliance. Incorporating education programs into daily care can enhance patient outcomes and alleviate healthcare cost.

Keywords: Diabetes mellitus, patient education, randomized controlled trial, random blood glucose (RBS), glycated haemoglobin (HbA1c).

INTRODUCTION

Diabetes mellitus, especially Type 2 Diabetes Mellitus (T2DM), is a growing global health problem, and it contributes to cardiovascular disease, renal insufficiency, and neuropathies (1). Diabetes management is successful with a multidisciplinary strategy involving pharmacological therapy, lifestyle change, and

organized patient education (2). Diabetes management despite advancements lingers out of reach for the majority of patients due to noncompliance with drugs, deficiency of proper suitable information regarding self-management, and the lack of support from the health care (3).

Programs of formal education for patients have been delineated as a central intervention for the optimization of diabetes outcomes with the augmented patient knowledge, adherence to medication, and reinforced self-care behaviors (4). As members of the patient care team, pharmacists' roles include active involvement for the treatment of diabetes through drug therapy management, lifestyle change counseling, and periodic evaluation of the treatment effectiveness (5). Pharmacists' educational interventions have been established as effective for patients' significant improvement of diabetes-related knowledge, empowerment as active participants of self-care, and achievement of better glycemic control as well as quality of life (6).

The study attempts to evaluate the effect of structured patient education on the treatment of diabetes by utilizing a controlled trial research methodology. The structured pharmacists' education and standard treatment would be provided for the intervention group, and standard diabetes treatment only would be provided for the control group. The study takes into consideration significant outcomes including the glycemic control, adherence to medication, and the improvement of quality of life for the patients. Through these standards, the study attempts to indicate the necessity for formal education as a standard component of caring for diabetes, particular for the different communities.

The research study is undertaken to determine the structured patient education's impact on glycemic control, drug adherence, and self-care activities in T2DM through a controlled trial, and the study includes a number of objectives to determine the quality of structured patient education in terms of improving glycemic control among T2DM patients, to determine the impact of planned patient education on drug adherence among T2DM patients, for the exploratory study to discover the contribution of structured patient education toward the improvement of patients' knowledge and diabetes self-management activities, and for the comparative study of the outcome of the formal patient education with the standard diabetes care.

MATERIALS AND METHODS

Study Design

This was a prospective, randomized, controlled trial done to evaluate the effect of patient education on the control of diabetes in patients with type 2 diabetes mellitus (T2DM). There were 48 T2DM patients who were allocated randomly into a control or intervention group. The groups were subdivided for better comparability in terms of the level of glycemic control (mild, moderate, and severe diabetes) with each subgroup containing eight patients.

Mild HTN (n=8)

Moderate HTN (n=8)

Severe HTN (n=8)

Study Population and Eligibility Criteria

Inclusion Criteria:

- Patients diagnosed with T2DM.
- Age ≥ 18 years.
- Adequate willingness to take part in the study and give informed consent.

Exclusion Criteria:

- Patients with secondary diabetes.
- Presence of serious comorbidities that interfere with treatment adherence.
- Patients who refuse to give informed consent.

Intervention Protocol

- The patient education program consisted of:
- Disease Awareness: Pathophysiology of T2DM, complications, and self-care information.
- Dietary Advice: Individualized dietary advice for improved glycemic control.
- Physical Activity Guidance: Exercise programs developed according to patient needs.
- Medication Adherence Support: Counselling on adherence importance, side effects, and correct medication use.

Follow-Up and Data Collection

Patients were followed up every 10 days for a cumulative period of three months. Clinical and behavioral information were gathered on each follow-up visit to evaluate the intervention's effectiveness.

Outcome Measures

Primary Outcomes:

- Improvement in Glycemic Control: Measured through Glycated Hemoglobin (HbA1c) and Random Blood Glucose (RBS) levels.
- Medication Adherence: Measured through the Morisky Medication Adherence Scale (MMAS).

Secondary Outcomes:

- Improvement in Patient Knowledge: Measured through set questionnaires.
- Quality of Life (QoL) Changes: Measured with validated QoL assessment instruments.

Statistical Analysis

- Paired t-tests for within-group comparisons (pre- and post-intervention).
- Chi-square tests for categorical data analysis.
- Analysis of Variance (ANOVA) to compare differences between stratified glycemic levels.

Ethical Considerations

Ethical approval was granted prior to the start of the study. Informed consent was obtained from all participants, with confidentiality and ethical research practices ensured.

RESULTS

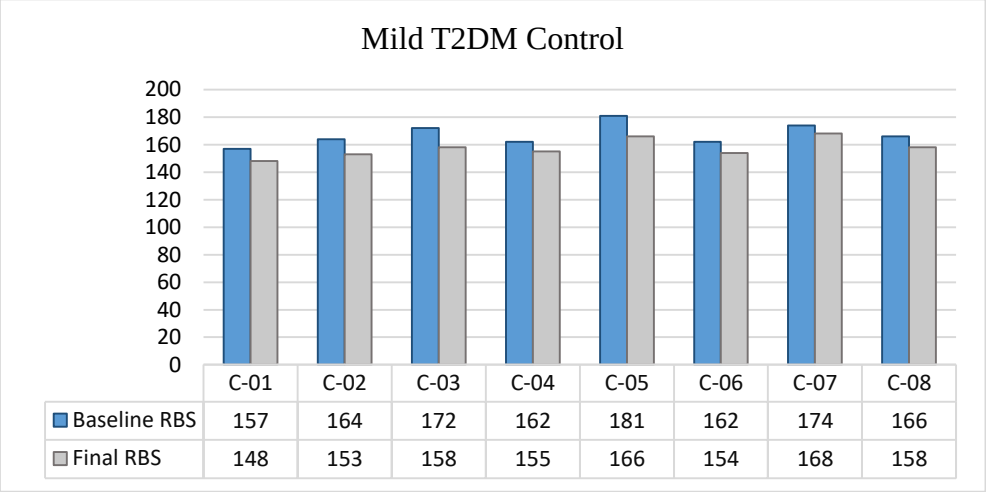
Table 1. Demographic Characteristics at Baseline

Variable	Control (N=24)	Intervention (N=24)
Gender		
Male	14 (58.33%)	14 (58.33%)
Female	10 (41.67%)	10 (41.67%)
Age (years)		

Mean (SD)	52.63 (8.56)	51.75 (10.11)
Min - Max	(38, 73)	(35, 75)

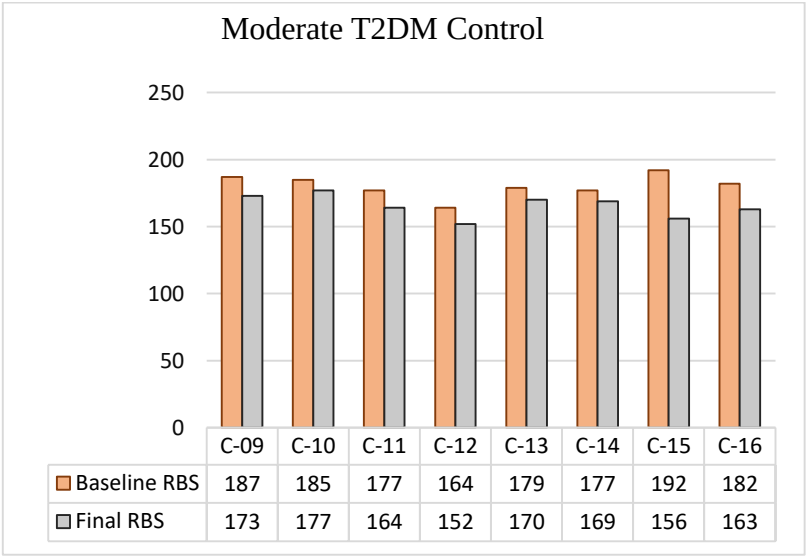
The given table describes the baseline demographic characteristics of participants in a study, segregating them into two groups: Control (N=24) and Intervention (N=24). For each group, gender and age data are presented. Gender Distribution- Both groups have an identical gender distribution, with 14 males (58.33%) and 10 females (41.67%) in each group. Age Distribution- The mean age in the Control group is 52.63 years with a standard deviation (SD) of 8.56 years, while in the Intervention group, the mean age is 51.75 years with an SD of 10.11 years. The age range in the Control group is from 38 to 73 years, and in the Intervention group, it is from 35 to 75 years. This table provides a clear comparison of the gender and age demographics between the control and intervention groups, confirming similar baseline characteristics in terms of these variables.

Graph 1. MILD T2DM (RBS) Control group



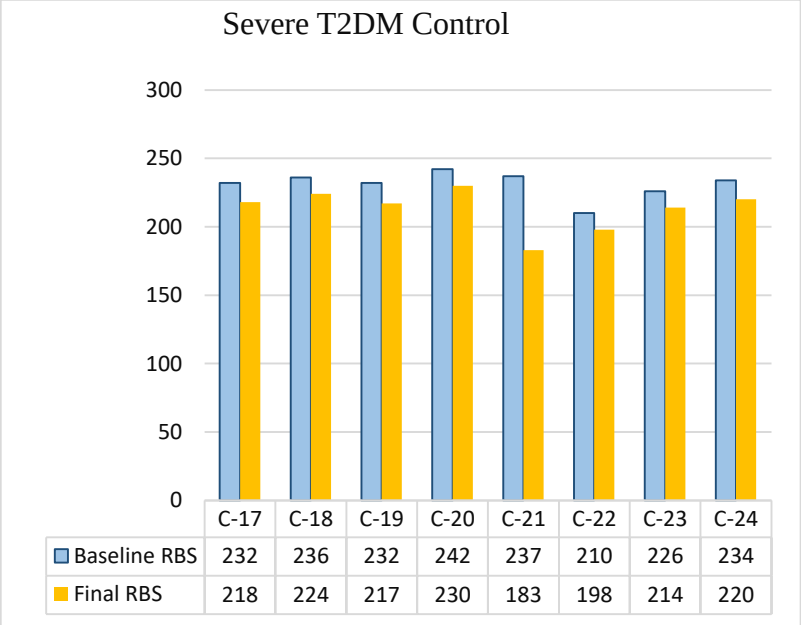
The graph shows RBS changes in individuals (C-01 to C-08) with mild T2DM who did not receive an intervention. RBS decreased slightly from 181 to 157 mg/dl at baseline 168 to 148 mg/dl at final measurement.

Graph 2. MODERATE T2DM (RBS) Control group



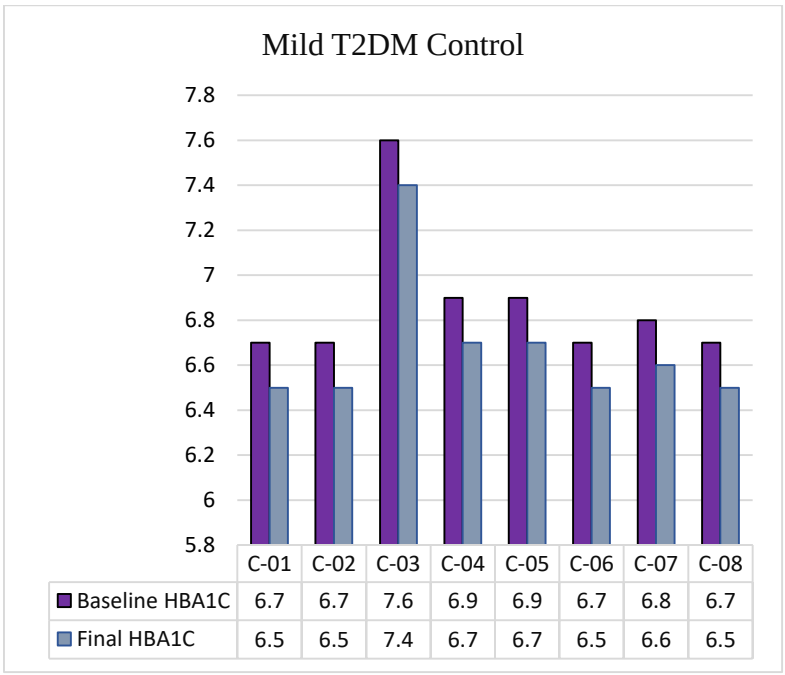
The graph shows RBS changes in individuals (C-09 to C-16) with moderate T2DM who did not receive an intervention. RBS decreased slightly from 192 to 164 mg/dl at baseline 177 to 152 mg/dl at final measurement.

Graph 3. SEVERE T2DM (RBS) Control group



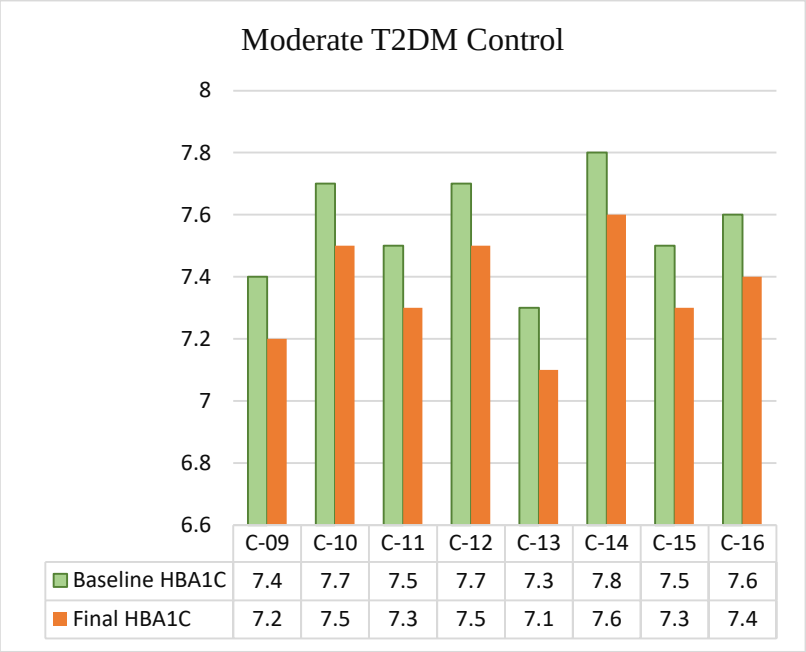
The graph shows RBS changes in individuals (C-17 to C-24) with severe T2DM who did not receive an intervention. RBS decreased slightly from 242 to 210 mg/dl at baseline 230 to 183 mg/dl at final measurement

Graph 4. MILD T2DM (HbA1C) Control group



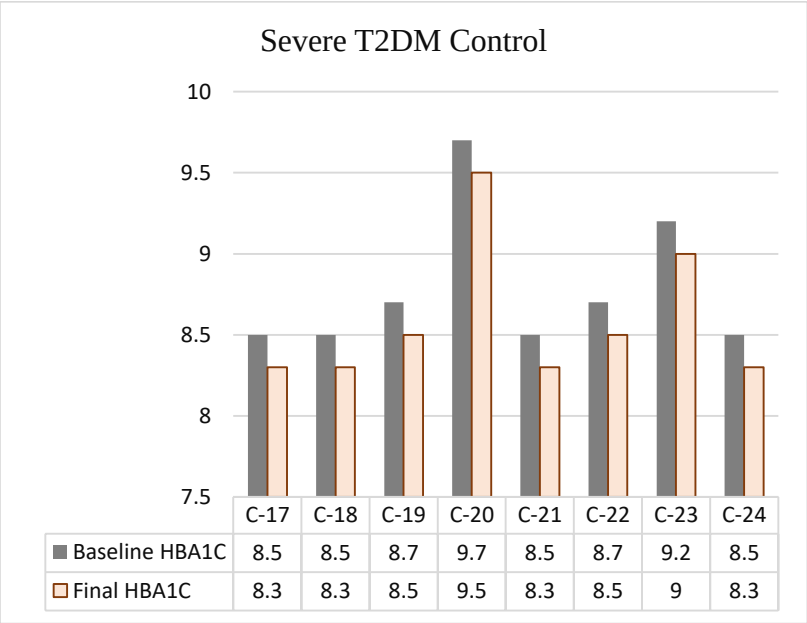
The graph shows Hb1Ac changes in individuals (C-01 to C-08) with mild T2DM who did not receive an intervention. Hb1Ac decreased slightly from 7.6 to 6.7% at baseline 7.4 to 6.5% at final measurement.

Graph 5. MODERATE T2DM (HbA1C) Control group



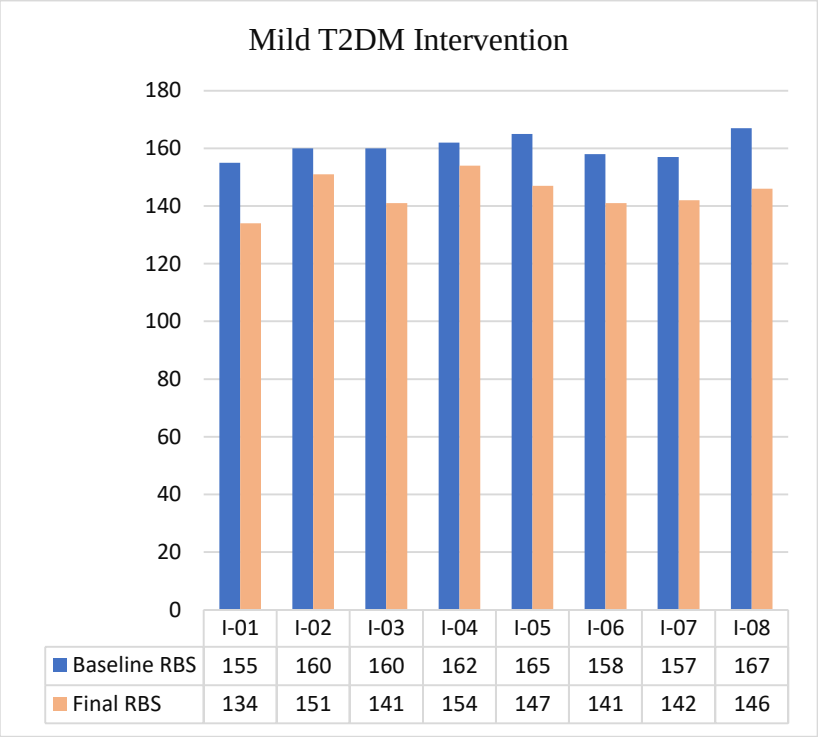
The graph shows Hb1Ac changes in individuals (C-09 to C-16) with moderate T2DM who did not receive an intervention. Hb1Ac decreased slightly from 7.8 to 7.3% at baseline 7.6 to 7.1% at final measurement.

Graph 6. SEVERE T2DM (HbA1C) Control group



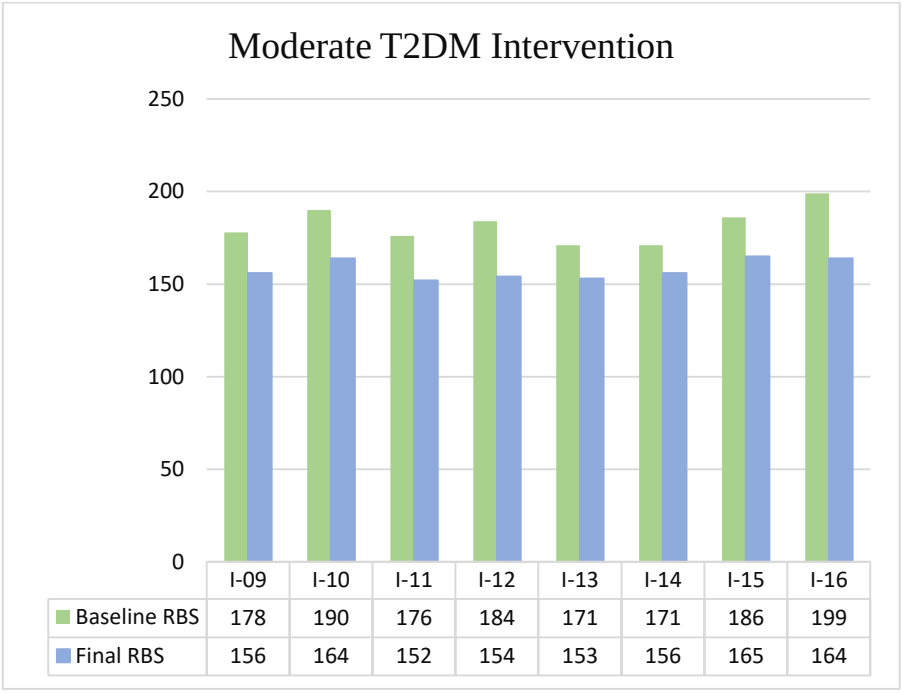
The graph shows Hb1Ac changes in individuals (C-17 to C-24) with severe T2DM who did not receive an intervention. Hb1Ac decreased slightly from 9.7 to 8.5% at baseline 9.5 to 8.3% at final measurement.

Graph 7. MILD T2DM (RBS) Intervention group



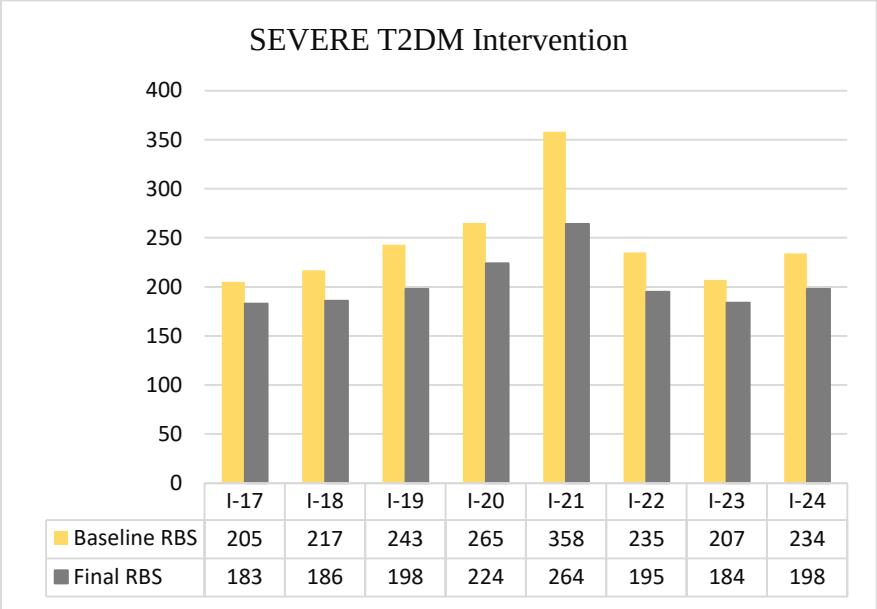
The graph shows RBS changes in individuals (I-01 to I-08) with mild T2DM before and after intervention. RBS initially ranged from 165 to 155mg/dl reducing to 154 to 134mg/dl after intervention.

Graph 8. MODERATE T2DM (RBS) Intervention group



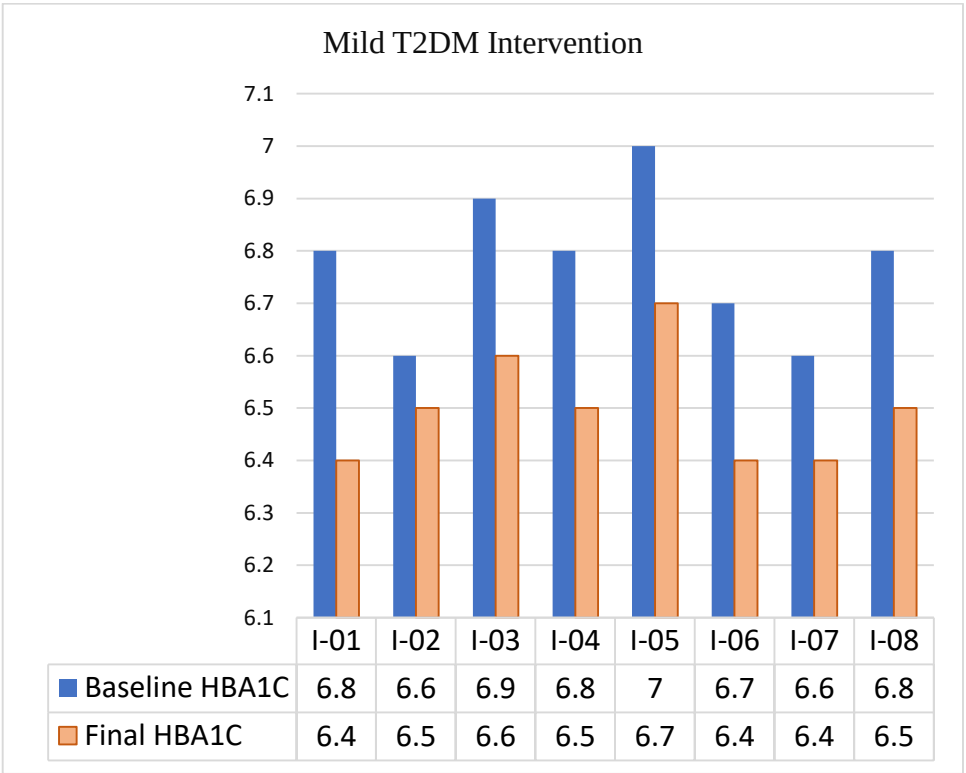
The graph shows RBS changes in individuals (I-09 to I-16) with moderate T2DM before and after intervention. RBS initially ranged from 199 to 171mg/dl reducing to 165 to 152mg/dl after intervention.

Graph 9. SEVERE T2DM (RBS) Intervention group



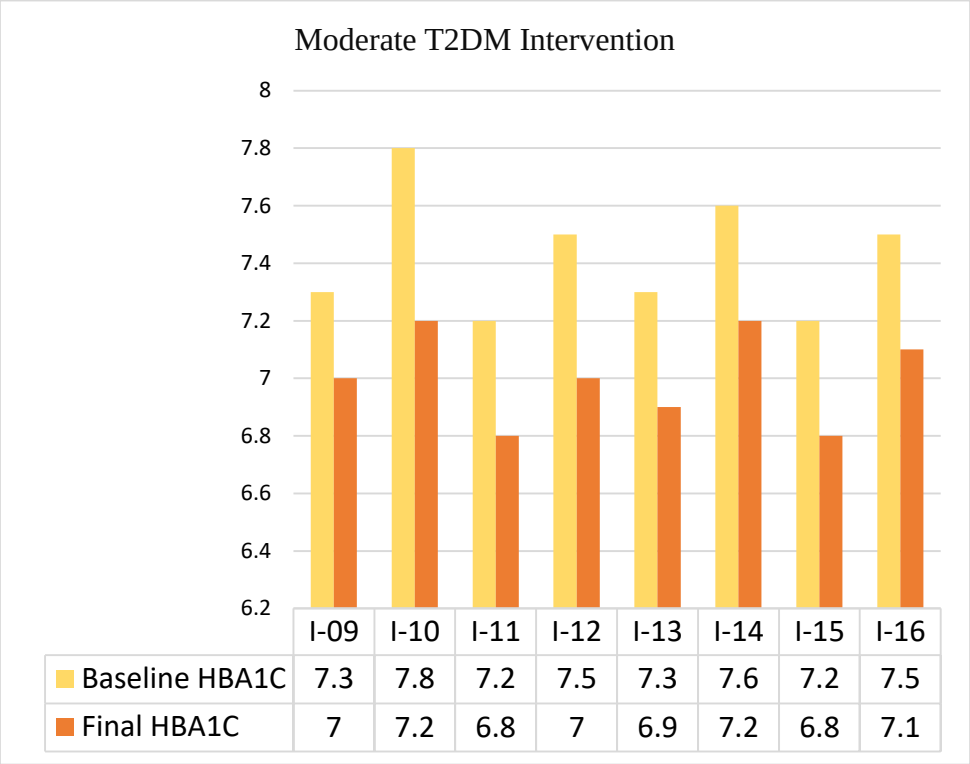
The graph shows RBS changes in individuals (I-17 to I-24) with severe T2DM before and after intervention. RBS initially ranged from 358 to 205mg/dl reducing to 264 to 183mg/dl after intervention.

Graph 10. MILD T2DM (HbA1C) Intervention group



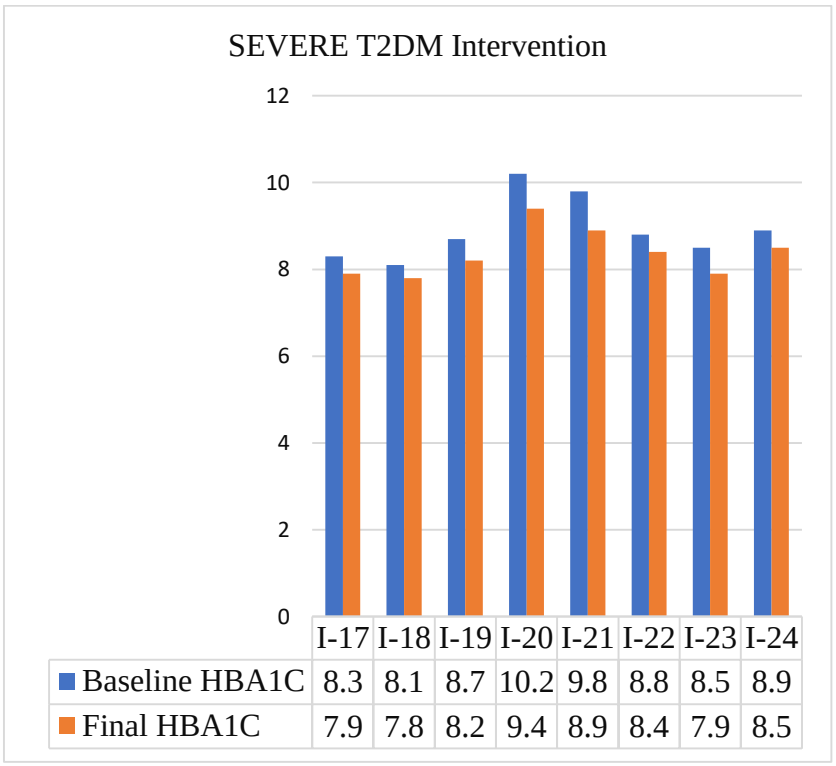
The graph shows Hb1Ac changes in individuals (I-01 to I-08) with mild T2DM before and after intervention. Hb1Ac initially ranged from 7to 6.6% reducing to 6.7 to 6.4% after intervention.

Graph 11. MODERATE T2DM (HbA1C) Intervention group



The graph shows Hb1Ac changes in individuals (I-09 to I-16) with moderate T2DM before and after intervention. Hb1Ac initially ranged from 7.8 to 7.2% reducing to 7.2 to 6.8% after intervention.

Graph 12. SEVERE T2DM (HbA1C) Intervention group



The graph shows Hb1Ac changes in individuals (I-17 to I-24) with severe T2DM before and after intervention. Hb1Ac initially ranged from 10.2 to 8.1% reducing to 9.4 to 7.8% after intervention.

DISCUSSION

This randomized controlled trial demonstrated that systematic education of the patient had a beneficial effect on glycemic control, medication adherence, and patient knowledge about type 2 diabetes mellitus (T2DM). The within-group analysis indicated a decrease in Random Blood Sugar (RBS) and HbA1c in the intervention group. For instance, RBS came down from 165–358 mg/dl to 134–183 mg/dl, and HbA1c came down from 7.0–10.2% to 6.4–7.8% after intervention. The control group also decreased modestly (RBS: 181–242 mg/dl to 148–183 mg/dl, HbA1c: 7.4–9.7% to 6.5–8.3%).

Statistical examination established relevant within-group differences ($t > 2.06$, $p < 0.05$), but between-group ANOVA did not yield statistically significant differences ($p > 0.05$), probably owing to the small sample size (n=48) and short follow-up period (3 months). Overall trends, however, establish the efficacy of structured education.

Medication adherence, scored on the MMAS-8 scale, improved significantly in the intervention arm, indicating the beneficial role of pharmacist counseling and reminder. Increased patient education and lifestyle change also helped in the decrease of hospital visits and increase in quality of life.

These results are also supported by existing literature on the potential of education by pharmacists to enhance adherence, self-management, and metabolic control in T2DM. Notably perhaps, structured education is especially useful in settings of resource limitation, like India, where increasing prevalence of T2DM imposes tremendous burdens on the health system.

Overall, there were clinically significant improvements in RBS, HbA1c, compliance, and quality of life following structured patient education, although the between-group differences were not statistically significant. The trial acknowledges the potential of pharmacist intervention in T2DM control but larger multicenter trials with longer follow-up will be required to confirm such benefits.

CONCLUSION

This study highlights the need for pharmacist intervention for diabetes care to improve not only glycemic control for T2DM patients but also medication adherence and patient education. In conclusion, lifestyle education and lifestyle counselling performed by pharmacists have high significant effects in reducing Random Blood Sugar (RBS) as well as HbA1c levels in the intervention group. The excellent improvement in treatment compliance measured by MMAS-8 also emphasizes the effect of direction of pharmacist for patient compliance and self care management. In addition, lower hospitalization rates and improved quality of life among the intervention group further substantiate the role of pharmacists in the care of patients with diabetes. Our data highlights how incorporating structured patient education and counselling into standard care can result in significant gains in the effectiveness of diabetes management and using health care resources efficiently.

Nevertheless, the study had a small sample size, short follow-up (3 months), and single-center design. Further studies need to be multi-center and designed with longer follow up periods to determine the long-term sustainability of community pharmacy-based intervention of T2DM management.

REFERENCES

1. Liu, Jinli et al. (2022). Low- and middle-income countries demonstrate rapid growth of type 2 diabetes: an analysis based on Global Burden of Disease 1990–2019 data. *Diabetologia*, 65(8), 1339-1352.
2. Davies, Melanie J. et al. (2022). Management of hyperglycaemia in type 2 diabetes, 2022. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of

Diabetes (EASD). *Diabetologia*, 65(12), 1925-1966.

3. Sridharan, Subha, Chittem, Mahati, and Muppavaram, Nagesh (2016). A review of literature on diabetes self-management: Scope for research and practice in India. *Journal of Social Health and Diabetes*, 04(02), 108-114.
4. Powers, Margaret A. et al. (2017). Diabetes Self-management Education and Support in Type 2 Diabetes. *The Diabetes Educator*, 43(1), 40-53.
5. Pousinho, Sarah et al. (2016). Pharmacist Interventions in the Management of Type 2 Diabetes Mellitus: A Systematic Review of Randomized Controlled Trials. *Journal of Managed Care & Specialty Pharmacy*, 22(5), 493-515.
6. Benedict, Amanda W. et al. (2018). Evaluation of a Pharmacist-Managed Diabetes Program in a Primary Care Setting Within an Integrated Health Care System. *Journal of Managed Care & Specialty Pharmacy*, 24(2), 114-122.