

Original article

## Study of Comparative Effectiveness of Lifestyle Interventions Versus Pharmacotherapy in the Long-Term Management of Type 2 Diabetes

<sup>1</sup>Dr. Nitin Sukadev Hivale, <sup>2</sup>Dr. Pallavi Pradip Gaikwad, <sup>3</sup>Dr. Firoz Mubarak Tadavi\*

<sup>1</sup>Ex Assistant Professor, B.J. Medical College, Pune

<sup>2</sup>Ex-BTO Incharge, Noble Hospital, Pune

<sup>3</sup>Professor (Additional), Department of Pharmacology, LTMMC & GH, Sion, Mumbai

Corresponding author: Dr. Firoz Mubarak Tadavi\*



### Abstract

**Background-** Type 2 diabetes mellitus (T2DM) is a prevalent chronic disease requiring effective long-term management strategies to prevent complications. Our study compares the long-term effectiveness of lifestyle interventions versus pharmacotherapy in managing T2DM.

**Methods-** A one-year randomized controlled trial was conducted with 60 T2DM patients, divided equally into a lifestyle intervention group and a pharmacotherapy group. The lifestyle group received dietary, physical activity, and behavioral therapy guidance, while the pharmacotherapy group was treated with standard diabetes medications. Key outcomes measured included HbA1c, BMI, cardiovascular health indicators (blood pressure, lipid profiles), and quality of life.

**Results-** The lifestyle intervention group showed a significantly greater reduction in HbA1c (-1.5% vs. -1.1%,  $p=0.03$ ) and BMI (-1.9 kg/m<sup>2</sup> vs. -0.5 kg/m<sup>2</sup>,  $p=0.01$ ) compared to the pharmacotherapy group. Improvements in cardiovascular health indicators were also more pronounced in the lifestyle group, with greater reductions in systolic and diastolic blood pressure, LDL cholesterol, and higher increases in HDL cholesterol. Quality of life scores increased significantly more in the lifestyle group (+13.6 vs. +7.8,  $p=0.02$ ).

**Conclusion-** Lifestyle interventions are more effective than pharmacotherapy in improving glycemic control, reducing BMI, enhancing cardiovascular health, and improving quality of life in T2DM patients. Integrating lifestyle modifications into diabetes care can significantly enhance treatment outcomes.

**Keywords-** Type 2 diabetes mellitus, lifestyle interventions, pharmacotherapy

### Introduction:

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and impaired insulin secretion, leading to hyperglycemia.(1) It poses significant health challenges globally, with increasing prevalence attributed to lifestyle factors such as poor diet, physical inactivity, and obesity.(2) Managing T2DM effectively is crucial to prevent complications like cardiovascular disease, neuropathy, nephropathy, and retinopathy. Traditional management strategies often include pharmacotherapy, which involves the use of medications such as metformin, sulfonylureas, and insulin to regulate blood glucose levels. (3)However, lifestyle interventions, including dietary modifications, increased physical activity, and behavioral therapy, have emerged as pivotal in T2DM management. These interventions target the root causes of insulin resistance and can offer sustainable long-term benefits without the side effects associated with pharmacotherapy.(4)

Our study aims to compare the long-term effectiveness of lifestyle interventions versus pharmacotherapy in managing T2DM. By analyzing various clinical outcomes, such as glycemic control, weight management, cardiovascular health, and quality of life, this research seeks to provide a comprehensive understanding of the benefits and limitations of both approaches.

### Methodology:

The study was conducted over a one-year period and included a sample size of 60 patients diagnosed with type 2 diabetes mellitus (T2DM). Participants were randomly assigned to one of two groups: the lifestyle intervention group or the pharmacotherapy group, with 30 patients in each group. Randomization ensured an unbiased distribution of potential confounding factors such as age, sex, baseline HbA1c levels, and body mass index (BMI). Ethical approval was obtained from the institutional review board, and informed consent was secured from all participants.

The lifestyle intervention group received comprehensive guidance on dietary changes, physical activity, and behavioral therapy. They participated in a structured program that included regular sessions with dietitians, exercise physiologists, and psychologists. The dietary component focused on a balanced, low-glycemic index diet, while the exercise regimen included moderate-intensity activities such as walking and cycling, aiming for at least 150 minutes of physical activity per week. Behavioral therapy sessions were conducted to support adherence and address any psychological barriers to lifestyle changes.

The pharmacotherapy group was treated according to standard clinical guidelines for T2DM

management. They received medications such as metformin, sulfonylureas, or insulin based on individual needs and clinical indications. Regular follow-ups were conducted to monitor medication adherence, adjust dosages, and manage any side effects. Both groups underwent quarterly assessments, which included measuring HbA1c, fasting blood glucose, BMI, blood pressure, lipid profiles, and quality of life using standardized questionnaires. Data collected from these assessments were analyzed to compare the long-term effectiveness of lifestyle interventions versus pharmacotherapy in managing T2DM.

## Results

**Table 1: Baseline Characteristics of Study Participants**

Characteristic	Lifestyle Intervention Group (n=30)	Pharmacotherapy Group (n=30)	p-value
Age (years)	52.3 ± 8.7	53.1 ± 9.2	0.68
Sex (Male/Female)	16/14	15/15	0.81
HbA1c (%)	8.5 ± 1.2	8.4 ± 1.3	0.75
BMI (kg/m <sup>2</sup> )	29.7 ± 4.5	30.2 ± 4.8	0.62
Duration of T2DM (years)	6.2 ± 3.1	6.5 ± 3.4	0.70

**Table 2: Change in HbA1c Levels**

Time Point	Lifestyle Intervention Group (%)	Pharmacotherapy Group (%)	p-value
Baseline	8.5 ± 1.2	8.4 ± 1.3	0.75
3 months	7.9 ± 1.1	7.8 ± 1.2	0.82
6 months	7.4 ± 1.0	7.5 ± 1.1	0.70
12 months	7.0 ± 0.9	7.3 ± 1.0	0.45
Change from Baseline	-1.5 ± 0.8	-1.1 ± 0.9	0.03

**Table 3: Change in Body Mass Index (BMI)**

Time Point	Lifestyle Intervention Group (kg/m <sup>2</sup> )	Pharmacotherapy Group (kg/m <sup>2</sup> )	p-value
Baseline	29.7 ± 4.5	30.2 ± 4.8	0.62
3 months	28.9 ± 4.2	30.0 ± 4.6	0.39
6 months	28.3 ± 4.0	29.8 ± 4.5	0.23
12 months	27.8 ± 3.8	29.7 ± 4.4	0.10
Change from Baseline	-1.9 ± 1.2	-0.5 ± 1.0	0.01

**Table 4: Change in Cardiovascular Health Indicators**

Indicator	Lifestyle Intervention Group	Pharmacotherapy Group	p-value
Systolic BP (mmHg)	-8.4 ± 6.5	-4.2 ± 5.7	0.02
Diastolic BP (mmHg)	-4.5 ± 4.0	-2.3 ± 3.8	0.04
LDL Cholesterol (mg/dL)	-15.3 ± 10.5	-10.2 ± 9.8	0.05
HDL Cholesterol (mg/dL)	+5.4 ± 3.8	+2.1 ± 2.9	0.01

**Table 5: Change in Quality of Life Scores**

Time Point	Lifestyle Intervention Group (score)	Pharmacotherapy Group (score)	p-value
Baseline	58.7 ± 10.2	59.1 ± 9.8	0.85
3 months	65.4 ± 9.5	62.3 ± 10.1	0.21
6 months	68.7 ± 8.7	64.5 ± 9.3	0.12
12 months	72.3 ± 7.8	66.9 ± 8.5	0.04
Change from Baseline	+13.6 ± 7.0	+7.8 ± 6.5	0.02

**Discussion:**

The study's results highlight significant insights into the comparative effectiveness of lifestyle interventions versus pharmacotherapy in the long-term management of type 2 diabetes mellitus (T2DM). Both treatment strategies have shown effectiveness in managing glycemic levels and improving various health outcomes, but with notable differences in specific areas.(6,7)

**Glycemic Control**

The primary outcome of interest in this study was glycemic control, measured by changes in HbA1c levels over the course of one year. Both groups exhibited significant reductions in HbA1c from baseline, demonstrating that both lifestyle interventions and pharmacotherapy are effective in lowering blood glucose levels. (8) However, the reduction in the lifestyle intervention group (-1.5%)

was significantly greater than in the pharmacotherapy group (-1.1%), with a p-value of 0.03, indicating a statistically significant difference. This suggests that lifestyle interventions may have a superior impact on glycemic control compared to pharmacotherapy alone. The greater reduction in HbA1c in the lifestyle intervention group can be attributed to the comprehensive approach targeting diet, physical activity, and behavioral changes, which directly address the root causes of insulin resistance and improve overall metabolic health.(9)

#### **Body Mass Index (BMI)**

The results concerning changes in BMI also favored the lifestyle intervention group. Participants in this group experienced a more substantial reduction in BMI (-1.9 kg/m<sup>2</sup>) compared to those in the pharmacotherapy group (-0.5 kg/m<sup>2</sup>), with a p-value of 0.01. This significant difference underscores the effectiveness of lifestyle modifications in achieving weight loss, a crucial component in managing T2DM. Weight loss contributes to improved insulin sensitivity, reduced inflammation, and better cardiovascular health. The structured dietary plans and increased physical activity in the lifestyle intervention group were likely key drivers of the observed weight loss, emphasizing the importance of non-pharmacological approaches in the holistic management of T2DM.(10)

#### **Cardiovascular Health Indicators**

Cardiovascular health, assessed through changes in blood pressure and lipid profiles, showed notable improvements in both groups, with more pronounced benefits in the lifestyle intervention group. Systolic and diastolic blood pressure reductions were significantly greater in the lifestyle group (-8.4 mmHg and -4.5 mmHg, respectively) compared to the pharmacotherapy group (-4.2 mmHg and -2.3 mmHg), with p-values of 0.02 and 0.04, respectively. Additionally, LDL cholesterol levels decreased more in the lifestyle group (-15.3 mg/dL) compared to the pharmacotherapy group (-10.2 mg/dL), with a p-value of 0.05. HDL cholesterol levels also improved more significantly in the lifestyle group (+5.4 mg/dL vs. +2.1 mg/dL), with a p-value of 0.01.

These findings indicate that lifestyle interventions have a more substantial impact on cardiovascular risk factors, which are critical in the management of T2DM given the high risk of cardiovascular disease in this population. The combination of diet and exercise in the lifestyle intervention group

likely contributed to these improvements by reducing arterial stiffness, improving lipid metabolism, and promoting overall cardiovascular health.

#### **Quality of Life**

Quality of life, an essential consideration in chronic disease management, showed significant improvements in both groups, with greater enhancements observed in the lifestyle intervention group. The increase in quality of life scores from baseline to 12 months was +13.6 in the lifestyle group compared to +7.8 in the pharmacotherapy group, with a p-value of 0.02. This suggests that lifestyle interventions not only improve clinical outcomes but also enhance overall well-being and life satisfaction. The psychological benefits of engaging in regular physical activity, adhering to a healthy diet, and achieving weight loss likely contributed to these improvements. Behavioral therapy sessions in the lifestyle group may have also played a role in supporting mental health and fostering a positive attitude towards disease management.

#### **Implications for Clinical Practice**

These findings have significant implications for clinical practice. They suggest that lifestyle interventions should be a cornerstone of T2DM management, potentially offering more substantial benefits than pharmacotherapy alone. While medications remain essential for many patients, especially those with advanced disease or specific comorbidities, integrating lifestyle modifications can enhance treatment efficacy, improve quality of life, and reduce the need for medications, thereby minimizing potential side effects.

Healthcare providers should prioritize patient education on the importance of diet and exercise, offer resources for behavioral support, and create individualized plans that consider the patient's lifestyle, preferences, and capabilities. Regular follow-up and encouragement can help maintain adherence to lifestyle changes, leading to sustained benefits.

Despite the encouraging results, this study has some limitations. The sample size was relatively small, and the study duration was limited to one year. Larger, long-term studies are needed to confirm these findings and assess the sustainability of lifestyle changes.

#### **Conclusion:**

In conclusion, our study demonstrates that lifestyle interventions are more effective than

pharmacotherapy in improving glycemic control, reducing BMI, enhancing cardiovascular health, and increasing quality of life in patients with T2DM. These findings support the integration of

comprehensive lifestyle modification programs into standard diabetes care, highlighting their potential to transform the management of T2DM and improve long-term outcomes for patients.

### References:

1. Sagastume D, Siero I, Mertens E, Cottam J, Colizzi C, Peñalvo JL. The effectiveness of lifestyle interventions on type 2 diabetes and gestational diabetes incidence and cardiometabolic outcomes: A systematic review and meta-analysis of evidence from low- and middle-income countries. *EClinicalMedicine*. 2022 Sep 9;53:101650.
2. Mozaffarian D, Afshin A, Benowitz NL, et al. Population approaches to improve diet, physical activity, and smoking habits: a scientific statement from the American heart association. *Circulation*. 2012;126:1514–1563.
3. Flood D, Hane J, Dunn M, et al. Health system interventions for adults with type 2 diabetes in low- and middle-income countries: a systematic review and meta-analysis. *PLoS Med*. 2020;17
4. Lindström J, Tuomilehto J. The diabetes risk score. *Diabetes Care*. 2003;26:725–731.
5. Sterne JAC, Savović J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. 2019;366:14898.
6. Schwarzer G. General Package for Meta-Analysis. R package version 5.2-0. 2022.
7. Raghuram N, Ram V, Majumdar V, et al. Effectiveness of a Yoga-Based Lifestyle Protocol (YLP) in preventing diabetes in a high-risk Indian cohort: a multicenter cluster-randomized controlled trial (NMB-Trial) *Front Endocrinol*. 2021;12
8. Wijesuriya M, Fountoulakis N, Guess N, et al. A pragmatic lifestyle modification programme reduces the incidence of predictors of cardio-metabolic disease and dysglycaemia in a young healthy urban South Asian population: a randomised controlled trial. *BMC Med*. 2017;15:146.
9. Yadav R, Yadav RK, Khadgawat R, Pandey RM. Comparative efficacy of a 12 week yoga-based lifestyle intervention and dietary intervention on adipokines, inflammation, and oxidative stress in adults with metabolic syndrome: a randomized controlled trial. *Transl Behav Med*. 2019;9:594–604.
10. Yadav R, Yadav RK, Khadgawat R, Pandey RM, Upadhyay AD, Mehta N. Randomized controlled trial of a 12-week yoga-based (including diet) lifestyle vs. dietary intervention on cardio-metabolic risk factors and continuous risk score in Indian adults with metabolic syndrome. *Behav Med*. 2020;46:9–20.