
**“EFFICACY OF INTEGRATED AYURVEDA TREATMENT
PROTOCOL IN UNCONTROLLED TYPE 2 DIABETES
MELLITUS-A RANDOMISED CONTROLLED CLINICAL TRIAL”**

**Thesis Submitted to
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**For the award of the degree of
Doctor of Philosophy
In the Faculty of Ayurveda (KAYACHIKITSA)**

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Dr. Suketha Kumari

LIST OF ABBREVIATIONS USED

T2DM	Type 2 Diabetes mellitus
HbA1C	Glycated hemoglobin
WHO	World health organization
ADA	American diabetes association
RCT	Randomized controlled trial
CAM	Complementary and alternative medicine
NCCIH	National Centre for alternative and Integrative Health
IDF	International Diabetes Federation
LDL	Low-density lipoprotein
FBS	Fasting blood sugar
PPBS	Post prandial blood sugar
FPG	Fasting plasma glucose
NIDDM	Non-insulin-dependent diabetes mellitus
BMI	Body mass index
PHF	Polyherbal formulation
CS	Charaka Samhita
SS	Sushruta Samhita
AH	Ashtanga Hridaya
MN	Madhava nidana
BP	Bhava prakasha

AS	Ashtanga sangraha
YR	Yoga Ratnakara
VS	Vanga sena
GI	Glycaemic index
RS	Resistant starch type 3
MUFA	Monounsaturated fatty acids
ISPAD	The International society for paediatric and adolescent diabetes
HDL	High density lipoprotein
USDA	United states department of agriculture
VLC	Very low carbohydrate diet
DASH	Dietary approach to Stop Hypertension
HIIT	High intensity interval training
IR	Immediate Release
ER	Extended Release
OS	Oxidative stress
OGTT	Oral glucose tolerance test
SGLT2	Sodium-glucose co-transporter-2
HOMA IR	Homeostatic model for assessment for insulin resistance
CAD	Coronary Artery Disease
SD	Standard deviation
CRF	Case report form case report form

DQOL	Diabetes Quality of Life
GCP	Good clinical practice
HB	Haemoglobin
KCAL	Kilocalorie
TC	Total cholesterol
VLDL	Very low-density lipoprotein
IF	Intermittent fasting
ADR	Adverse drug reaction.

TABLE OF CONTENTS

SL. NO.		PARTICULARS	PAGE NO.
1.	1.1	ABSTRACT	xxx-xlii
	1.2	INTRODUCTION	1-5
	1.3	BACKGROUND	6-10
2.		AIM & OBJECTIVES	11
3.		REVIEW OF LITERATURE: • Disease review • Chikitsa • <i>Pathya Apathya</i> • Review of Type 2 Diabetes mellitus • Diet and lifestyles measures in Type 2 diabetes mellitus • Drug review	12-74
4.		JUSTIFICATION	75-77
5.		MATERIAL AND METHODS	78-93
	5.1	Pharmaceutical study	
	5.2	Analytical study	
	5.3	Clinical Study	
6.		OBSERVATION AND RESULTS	94-159
	6.1	Quality Control & Analytical results of <i>Madhumehari ghana vati</i>	
	6.2	Clinical study results	
7.		DISCUSSION	160-180
8.		SUMMARY	181-182

9.		CONCLUSION	183
10.		LIMITATIONS OF THE STUDY	184
11.		RECOMMENDATIONS FOR FURTHER STUDY	185
12.		BIBLIOGRAPHY	186-209
13.		ANNEXURES	210-281

LIST OF TABLES

SL NO	TABLE CONTENT	PAGE NO
1.	Table no 1. Showing the <i>aharaja nidana</i> of <i>Prameha</i>	13
2.	Table no 2. Showing <i>viharaja nidana</i> of <i>Prameha</i>	14
3.	Table no.3. Views of <i>Purva roopa</i> and <i>roopa's</i> of <i>prameha</i> in <i>brahatrayi</i>	15
4.	Table no.4. Classical <i>provaroopa</i> and <i>roopa's</i> of <i>Prameha</i>	16
5.	Table no.5. Classification of <i>Prameha</i>	17
6.	Table no.6: Types of <i>prameha</i> as per brahatrayi	18-19
7.	Table no. 7. Showing <i>Pathya ahara</i> in <i>Prameha</i>	38-39
8.	Table no 8. Showing <i>Pathya vihara</i> in <i>Prameha</i>	39-40
9.	Table no 9. Showing <i>Yoga</i> in <i>Prameha</i>	40-41
10.	Table no 10. Showing <i>Apathya ahara</i> and <i>Vihara</i> in <i>Prameha</i>	42
11.	Table no 11. Showing different cooking methods in India	44-46
12.	Table no 12. Showing physical activity protocol as per ADA	59-61
13.	Table no 13. Oral drugs in T2DM	61-62
14.	Table no.14. Madhumeha ghana vati, latin name, rasa, guna, veerya, vipaka and Prabhava	72-73
15.	Table no 15. Showing mode of action of <i>Madhumehari ghanavati</i>	73-74
16.	Table no 16. Showing ingredients and proportion of <i>Madhumehari ghanavati</i>	79

17.	Table no.17: Showing patient allocation and group details	84
18.	Table no 18. Therapeutic <i>yoga</i> techniques with appropriate duration and remarks	89-90
19.	Table no 19. Assessment parameters	91
20.	Table no 20. Analytical report of <i>Madhumehari ghanavati</i> (macroscopic)	94
21.	Table no 21. Analytical report of <i>Madhumehari ghanavati</i> (microscopic)	95
22.	Table no 22. Age wise distribution of patients	97
23.	Table no 23. Gender wise distribution of patients	98
24.	Table no 24. Religion wise distribution of patients	98
25.	Table no 25. Education status wise distribution of patients	99
26.	Table no 26. Occupation wise distribution of patients	100
27.	Table no 27. Socioeconomic status wise distribution of patients	100
28.	Table no 28. Marital status wise distribution of patients.	101
29.	Table no 29. Desha wise distribution of patients	102
30.	Table no 30. Type 2 Diabetes chronicity and medication duration and dosage	102
31.	Table no 31. Family history wise distribution of patients	103
32.	Table no 32. Personal history wise distribution of patients	104
33.	Table no 33. Sleep wise distribution of patients	105
34.	Table no 34. Appetite wise distribution of patients	105

35.	Table no 35. Diet wise distribution of patients	106
36.	Table no 36. Showing physical activity wise distribution of patients	107
37.	Table no 37. Showing mental status wise distribution of patients	107
38.	Table no 38. Emotional status wise distribution of patients	108
39.	Table no 39. Habit wise distribution of patients	109
40.	Table no 40. Built wise distribution of the patients	110
41.	Table no 41. <i>Prakrati</i> wise distribution of subject	111
42.	Table no 42. <i>Saara</i> wise distribution of patients.	111
43.	Table no.43: Comparison of STP and IATP with calories given in KCAL by independent t test	112
44.	Table no.44: Comparison of STP and IATP with status of Adverse events	113
45.	Table no 45. Comparison of STP and IATP with Diet adherence, Yoga, and exercise adherence by independent t test	113-114
46.	Table no.46: Comparison of STP and IATP with weight in kg”s before and after intervention using unpaired ‘t’ test.	115
47.	Table no.47: Comparison of weight in kg’s in within STP and IATP paired ‘t’ test.	115
48.	Table no.48: Comparison of STP and IATP with BMI at before and after intervention by unpaired ‘t’ test.	116
49.	Table no.49: Comparison of different treatment time points with BMI in STP and IATP by paired ‘t’ test.	117
50.	Table no.50: Comparison of STP and IATP with waist circumference in cm before and after intervention using unpaired ‘t’ test	118

51.	Table no.51: Comparison of different treatment time points with waist circumference in cm in STP and IATP by paired ‘t’ test.	118
52.	Table no.52: Comparison of STP and IATP with Body fat (%) at different treatment time points by unpaired t test	119
53.	Table no.53: Comparison of different treatment time points with Body fat (%) in STP and IATP by paired t test	120
54.	Table no.54: Comparison of STP and IATP with visceral fat (%) at before and after intervention with paired ‘t’ test	121
55.	Table no.55: Comparison of different treatment time points with visceral fat (%) in STP and IATP by paired ‘t’ test	121
56.	Table no.56: Comparison of STP and IATP with Body Surface Area at different treatment time points by unpaired ‘t’ test	122
57.	Table no.57: Comparison of different treatment time points with Body Surface Area in STP and IATP by paired t test	123
58.	Table no.58: Comparison of STP and IATP with hemoglobin (HB) in % before and after intervention by unpaired ‘t’ test.	124
59.	Table no.59: Comparison of HB in % within STP and IATP by paired ‘t’ test	124
60.	Table no.60: Comparison of STP and IATP with HbA1C before and after intervention by unpaired ‘t’ test	125
61.	Table no.61: Comparison of different treatment time points with HbA1C in STP and IATP by paired ‘t’ test.	126
62.	Table no.62: Comparison of STP and IATP with FBS before and after intervention by unpaired ‘t’ test.	127

63.	Table no.63: Comparison of different treatment time points with FBS in STP and IATP by paired ‘t’ test.	127
64.	Table no.64: Comparison of STP and IATP with PPBS at different treatment time points by unpaired ‘t’ test.	128
65.	Table no.65: Comparison of different treatment time points with PPBS in STP and IATP by paired ‘t’ test.	129
66.	Table no.66: Comparison of STP and IATP with Fasting Insulin in miU/L before and after intervention by unpaired ‘t’ test.	130
67.	Table no.67: Comparison of different treatment time points with Fasting Insulin in miU/L in STP and IATP by paired ‘t’ test.	130
68.	Table no.68: Comparison of STP and IATP with HOMA-IR before and after intervention by unpaired ‘t’ test.	131
69.	Table no.69: Comparison of different treatment time points with HOMA-IR in STP and IATP by paired ‘t’ test.	132
70.	Table no.70: Comparison of STP and IATP with Total cholesterol (TC) before and after intervention unpaired ‘t’ test.	133
71.	Table no.71: Comparison of different treatment time points with Total cholesterol in STP and IATP by paired ‘t’ test	133
72.	Table no.72: Comparison of STP and IATP with High density lipoprotein (HDL) before and after intervention by unpaired ‘t’ test.	134
73.	Table no.73: Comparison of different treatment time points with HDL in STP and IATP by paired ‘t’ test.	135
74.	Table no.74: Comparison of STP and IATP with low density lipoprotein (LDL) at before and after intervention by unpaired ‘t’ test.	136

75.	Table no.75: Comparison of different treatment time points with LDL in STP and IATP by paired ‘t’ test	136
76.	Table no.76: Comparison of STP and IATP with Very low-density lipoprotein (VLDL) before and after intervention by unpaired t test.	137
77.	Table no.77: Comparison of different treatment time points with VLDL in STP and IATP by paired t test.	138
78.	Table no.78: Comparison of STP and IATP with Sr Triglycerides before and after interventions by unpaired ‘t’ test.	139
79.	Table no.79: Comparison of different treatment time points with Sr Triglycerides in STP and IATP by unpaired ‘t’ test	139
80.	Table no 80: Comparison of STP and IATP with Sr Creatinine at different treatment time points by unpaired ‘t’ test	140
81.	Table no.81: Comparison of different treatment time points with Sr Creatinine in STP and IATP by paired ‘t’ test	141
82.	Table no.82: Comparison of STP and IATP with satisfaction scores at different treatment time points by unpaired ‘t’ test	142
83.	Table no.83: Comparison of different treatment time points with satisfaction scores in STP and IATP by paired t test	142-143
84.	Table no.84: Comparison of STP and IATP with impact scores at different treatment time points by independent t test	144
85.	Table no.85: Comparison of different treatment time points with impact scores in STP and IATP by dependent t test	145
86.	Table no.86: Comparison of STP and IATP with Concerns: Social/Vocational at different treatment time points by Mann-Whitney U test	146

87.	Table no.87: Comparison of different treatment time points with Concerns: Social/Vocational in STP and IATP by Wilcoxon matched pairs and Friedman's ANOVA test	147-148
88.	Table no.88: Comparison of STP and IATP with Concerns Related to DM at different treatment time points by Mann-Whitney U test.	149
89.	Table no.89: Comparison of different treatment time points with Concerns Related to DM in STP and IATP by Wilcoxon matched pairs and Friedman's ANOVA test.	150
90.	Table no.90: Comparison of STP and IATP with DM QOL total scores at different treatment time points by independent t test	151-152
91.	Table no.91: Comparison of different treatment time points with DM QOL scores in STP and IATP by dependent t test	152
92.	Table no.92: Effect on Prameha purvaroop variables using Mann-Whitney U test (between the groups) and Wilcoxon matched pairs (within the group).	153-154
93.	Table no.93: Effect on Prameha roopa variables using Mann-Whitney U test (between the groups) and Wilcoxon matched pairs (within the group).	155-156
94.	Tab no 94: Showing Result summary	158-159

LIST OF IMAGES/FIGURE

SL NO	IMAGE/FIGURE NAME	PAGE NO
1.	Fig.01. <i>Prameha samprapti</i>	23
2.	Fig.02. Chikitsa sutra of <i>Prameha</i>	33
3.	Fig.03. Pathogenesis of T2DM	52
4.	Fig.04. Drug preparation steps.	80
5.	Image 1: Showing raw materials used in the Madhumehari ghanavati preparation	81
6.	Image 2: Showing <i>Madhumehari ghanavati</i> preparation	82
7.	Image 3: Showing <i>Madhumehari ghanavati</i> finished and packed product	83
8.	Fig.05: Consort chart	96

LIST OF GRAPH / BAR DIAGRAMS

SL NO	GRAPH NAME	PAGE NO
1.	Graph no.01: Showing demographic variable (Age, sex, religion, education)	99
2.	Graph no.2: Showing occupation, socioeconomic status, and marital status	101
3.	Graph no.3: T2DM Chronicity and medication duration	103
4.	Graph no.4: Showing family history of T2DM and metabolic syndrome.	104
5.	Graph no.5: Showing personal history wise distribution of patient [Bowel, sleep, appetite, Diet]	106
6.	Graph no.6 Showing physical activity and mental status wise distribution of patients.	108
7.	Graph no.7: Habits wise distribution of the patient	109
8.	Graph no.08: Built wise distribution of the patient.	110
9.	Graph no.09: Comparison of STP and IATP with calorie Given in KCAL	112
10.	Graph no.10: Comparison of STP and IATP with Calorie Given, Diet adherence %, Yoga/Exercised adherence %	113
11.	Graph no.11: Comparison of STP and IATP with weight in kgs at different treatment time points	116
12.	Graph no.12: Comparison of STP and IATP with BMI at different treatment time points	117

13.	Graph no.13: Comparison of STP and IATP with waist circumference in cm at different treatment time points	119
14.	Graph no.14: Comparison of STP and IATP with Body fat (%) at different treatment time points	120
15.	Graph no.15: Comparison of STP and IATP with visceral fat (%) at different treatment time points	122
16.	Graph no. 16: Comparison of STP and IATP with Body Surface Area at different treatment time points	123
17.	Graph no.17: Comparison of STP and IATP with HB in % at different treatment time points	125
18.	Graph no.18: Comparison of STP and IATP with HbA1C at different treatment time points	126
19.	Graph no.19. Comparison of STP and IATP with FBS at different treatment time points	128
20.	Graph no.20: Comparison of STP and IATP with PPBS at different treatment time points	129
21.	Graph no.21: Comparison of STP and IATP with Fasting Insulin in miU/L at different treatment time points	131
22.	Graph no.22: Comparison of STP and IATP with HOMA-IR at different treatment time points	132
23.	Graph no.23: Comparison of STP and IATP with Total cholesterol at different treatment time points	134
24.	Graph no.24: Comparison of STP and IATP with HDL at different treatment time points	135

25.	Graph no 25: Comparison of STP and IATP with LDL at different treatment time points.	137
26.	Graph no.26: Comparison of STP and IATP with VLDL at different treatment time points	138
27.	Graph no.27: Comparison of STP and IATP with Sr Triglycerides at different treatment time points	140
28.	Graph no.28: Comparison of STP and IATP with Sr Creatinine at different treatment time points	141
29.	Graph no.29: Comparison of STP and IATP with satisfaction scores at different treatment time points	143
30.	Graph 30: Comparison of STP and IATP with impact scores at different treatment time points	147
31.	Graph no.31: Comparison of STP and IATP with Concerns: Social/Vocational at different treatment time points	148
32.	Graph no.32: Comparison of STP and IATP with Concerns Related to DM at different treatment time points	151
33.	Graph no.34: Comparison of STP and IATP with DM QOL total scores at different treatment time points	153

1.1 ABSTRACT

Introduction: Type 2 Diabetes Mellitus (T2DM) is a metabolic condition characterized by insulin resistance and pancreatic β -cell dysfunction caused by uncontrolled hyperglycaemia. There is also a link of inflammation in the pathogenesis of T2DM. T2DM is a growing concern worldwide, having reached epidemic proportions in many developing and most developed countries. According to American Diabetes Association, uncontrolled T2DM is measured as a glycated hemoglobin level (HbA1C) of $>7\%$. Diabetes is a major cause of blindness, kidney failure, heart attacks, stroke, and lower limb amputation. In 2016, an estimated 1.6 million deaths were directly caused by diabetes. Another 2.2 million deaths were attributable to high blood glucose in 2012. Almost half of all deaths attributable to high blood glucose occur before the age of 70 years. WHO estimates that diabetes was the seventh leading cause of death in 2016. The treatment of T2DM begins with a thorough and interdisciplinary strategy. The American Diabetes Association's (ADA) treatment guidelines emphasize medical nutrition therapy, exercise, pharmaceutical therapy, and the prevention and control of diabetes-related complications. ADA recommends, metformin is the only medicine shown in randomized controlled trials (RCTs) to reduce mortality and complications. Additional drugs should be introduced in a patient-centred, customized manner, although there is no evidence from RCTs that any of these medications lower the risk of diabetes-related complications, cardiovascular mortality, or all-cause mortality. A 2011 comparative efficacy evaluation found that metformin, second-generation sulfonylureas, thiazolidinediones, and repaglinide (Prandin) reduced A1C levels by roughly 1% when used alone, and that combination therapies had an additive effect on A1C levels. Medications used to manage type 2 diabetes have a variety of negative effects such as nausea, diarrhoea,

abdominal bloating, weight loss or gain, and hypoglycaemia etc. Insulin therapy should be initiated if a patient fails to achieve glycaemic goals, is used as an initial treatment for type 2 diabetes in metabolic decompensation, or in cases of decompensated renal or hepatic insufficiency, myocardial infarction, stroke, acute severe illness, or major surgery.

Ayurveda classics describe the etiological factors of *Prameha* as sedentary activities, early introduction of milk and its products, animal feed cultivated especially in swampy areas, newly harvested grains, and refined sugars, etc., which have more similarities with the aetiology of T2DM.

Ayurveda classics defines *Prameha* as a set of complex clinical disorders characterized by frequent abnormal micturition, with the etiology involving genetic predisposition as well as improper diet and lifestyle. The clinical conditions described in *prameha* have much in common with diabetes mellitus. Ayurveda recommends different treatment modalities in *prameha* such as *nidana parivarjana* (preventive strategies), *shodana* (Detoxification), *shamana* (internal medication) and *pathyapathya* (diet and lifestyle restriction).

Integrated medicine (also known as integrated medicine) is the practice of strategically incorporating parts of complementary and alternative medicine into complete treatment strategies. Integrated medicine through complementary and alternative medicine (CAM) or "complementary health approaches" is a range of different medical and health-care techniques and products that are not now regarded to be part of traditional medicine. These include, yoga, chiropractic and osteopathic manipulation, meditation, massage therapy, acupuncture, relaxation techniques, tai chi, qi gong, healing touch, hypnosis, and movement therapies are some of the

options. Other complementary health approaches include traditional healers, Ayurvedic medicine, traditional Chinese medicine, homeopathy, and naturopathy. Researchers are currently exploring the potential benefits of integrative approach in a variety of medical conditions including pain management, different neurological conditions, cancer symptoms and treatment side effects, cardiology etc. Integrative approach can be beneficial in T2DM because most of which involve self-management, healing approaches and lifestyle changes. Ayurveda herbs have insulin sensitivity, anti-hyperglycemic, anti-hyper lipidemic, antioxidant properties etc. have beneficial effects in T2DM. Ayurveda dietetics have positive results in insulin resistance. Yoga (which includes Surya namaskar, Asanas, pranayama, and meditation) has proven a successful complimentary alternative in T2DM.

Objective:

Primary Objective: To evaluate the efficacy of Integrated Ayurveda treatment protocol as add-on therapy in patients of uncontrolled T2DM in achieving the glycemic control assessed through HbA1C

Secondary Objective: To compare the effect of Integrated Ayurveda treatment protocol and Standard treatment regimen intervention on changes in biochemical parameters of T2DM (Fasting Insulin, HOMA IR, Lipid profile) and quality of life

Hypothesis

Null hypothesis: Integrated Ayurveda treatment protocol which includes Ayurveda drug, diet and yogic intervention given for duration of 90 days is not equivalent to standard treatment protocol in uncontrolled Type 2 Diabetes Mellitus.

Alternate Hypothesis: Integrated Ayurveda treatment protocol which includes Ayurveda drug, diet and yogic intervention given for duration of 90 days is equivalent to standard treatment protocol in uncontrolled Type 2 Diabetes Mellitus.

Materials and Methods: Methodology for the study is described under following headings:

1. Pharmaceutical study
2. Analytical study
3. Clinical study

1. Pharmaceutical study:

- **Identification & Authentication:** Raw drugs of *Madhumehari ghanavati* were identified and authenticated in the AYUSH certified ASU drug testing Central research facility of KAHER'S Shri B.M.K. Ayurveda Mahavidyalaya, Belagavi.
- **Collection:** Raw drugs of *Madhumehari ghanavati* were procured from KLE Ayurveda Pharmacy, Khasbag, Belagavi.
- **The procedure of Preparation of Trial Drug**
 - All coarse powders were taken in *khalva yantra* and a homogenous mixture was prepared. Drug mixture was taken in stainless steel container and soaked in eight parts of tap water for 12 hrs. Overnight soaked drug mixture was kept for boiling on moderate fire till it reduced to one fourth quantity. Pleasant odor of *Kashaya* was observed during boiling which is later filtered and kept aside. The *Kashaya* was taken in stainless steel vessel and kept for boiling. The boiling continued till it attained the semisolid consistency. After attaining

semisolid consistency, the vessel was removed from gas. It was taken in a thick polythene sheet when it was warm and kept in shade for drying. After drying completely, it was powdered, and a size of 500 mg ghanavati was prepared and stored in an airtight container.

3. Clinical Study:

- The medical trial received approval from the KAHER ethical committee for human subjects (Ref ID: KAHER/EC/20-21/001/11). The institutional ethical committee approval was obtained to conduct clinical study (BMK/21/PhD/SK). Study was registered in Clinical trial for Registry of India (CTRI/2020/12/029762).
- Study Design:
 - The study was a randomized, standard controlled, parallel group, open label, single centric trial.
 - The study employed a block design for randomization, ensuring a balanced 1:1 allocation ratio between control and trial groups.
 - The random sequence generation is through online software and the principal investigator managed online random sequence generation and opaque envelope sealing for allocation concealment which were blinded by the investigator.
 - The administration, distribution, and randomization of study-related materials were handled by different research teams.
- Two hundred subjects diagnosed with T2DM were included for the randomized controlled clinical trial from Ayurveda Hospital of KLE academy of higher education (KAHER, Karnataka, India) during October 2021 to

November 2022. T2DM subjects with insufficient blood glycemic control [Glycated hemoglobin (HbA1c:7 to 10.5 %)] while on stable treatment with metformin (≥ 1000 mg/day), aged between 18 to 70 years of either sex were considered for the study. Subjects with Uncontrolled Hypertension ($\geq 140/90$ mmHg), Cardiovascular diseases, Cerebrovascular accidents, or Microvascular complications of T2DM were excluded.

- Patients in the study were known cases of T2DM receiving stable metformin therapy (≥ 1000 mg/day) with inadequate glycemic control. In accordance with the randomization table, each patient was divided into one of two interventional groups.
- Control intervention i.e Standard treatment group (STP) intervened with customary T2DM treatment. This approach includes nutritional and lifestyle management counseling together with a stable dose of metformin (≥ 1000 mg/day). Any sort of activity, such as walking, jogging, swimming, or cycling, for at least 150 minutes per week (or 3 to 7 days per week, with no more than 2 days without exercise) at a spirited to moderate speed was advised.
- The study (trial) intervention Integrated Ayurveda treatment group (IATP) intervened with an integrated therapy regimen as an intervention. This includes metformin (≥ 1000 mg/day), polyherbal Ayurveda formulation Madhumehari ghanavati of 500 mg taken two tablets three times day after meals with water, an Ayurveda diet, and therapeutic yoga exercises.
- **Primary outcome measure.**
 - Glycated hemoglobin (HbA1c) (%)
- **Secondary outcome measure**

- Fasting insulin(miU/l), Homa IR(mg/dl), Fasting blood glucose (FBG in mg/dl),Post prandial blood glucose (PPBG in mg/dl),Urine glucose (Fasting and post prandial), weight (Kgs), BMI, waist circumference(in cm), Whole body fat percent(%), Visceral fat percent(%), Body surface area, lipid profile (Total cholesterol (mg/dl), HDL (mg/dl), LDL(mg/dl), VLDL(mg/dl), Triglycerides(mg/dl)) and Diabetes quality of life (DQOL).
- **Assessment interval**
 - HbA1c, Homa IR, Fasting insulin, lipid profile, hemoglobin and Serum creatinine, whole body fat percent, visceral fat percent and body surface area were assessed at baseline and on 90th day of interventions. FBG, PPBG, weight, BMI, waist circumference and DQOL were measured at baseline, 30th, 60th and 90th day of interventions.
- **Observation and Result**
 - A total of 200 patients were recruited for the study. Twelve patients in STP and six in the IATP group discontinued treatment due to different reasons. There were no discontinuations or withdrawals due to adverse events. In total, 12 individuals in this trial reported mild adverse effects.
 - The study found that both groups were similar in terms of gender (p=0.42), education (p=0.13), socioeconomic position (p=0.13), occupation (p=0.85), diet (p=0.19), lifestyle factors (p=0.29), appetite (p=0.740), sleep (p=0.8850), calorie intake (p=0.059) and a family history of T2DM (p=0.29. However, there were significant differences in age distribution (p=0.02), marital status (p=0.04), mean T2DM

chronicity ($p=0.01$), medication duration ($p=0.02$), and metformin dosage ($p=0.001$). Diet adherence ($p=0.001$) and exercise/yoga practice adherence ($p=0.001$) were more in the IATP group compared to the STP group. Demographic data analysis showed a distribution of patients with an age over 61 years (43%) followed by 51-60 years (34%) in STP and above 61 years (35%) followed by 41-60 years (24%) in IATP. Gender distribution showed more of men (53%) than women (46%); majority were married (88%); and below graduate (62%) to graduate (35%), respectively. Participants had a normal sleep schedule (60%), a moderately active (55%) to sedentary lifestyle (39%), and a normal to low appetite (81%). IATP (85.5%) had a good rate of diet and exercise adherence compared to STP (80.39%).

- Study data indicates that, between the groups, weight reduction was more significant in IATP ($p<0.001$) than STP. Within the group, both STP and IATP had a significant reduction in weight (in kg's) from before to after intervention ($p<0.001$). In BMI parameter also, IATP had significant changes ($p<0.001$) compared to STP. Within the group, both STP and IATP showed statistical significance in BMI measures ($p<0.001$). Effect of the intervention on waist circumference between the group showed that IATP group is better ($p<0.001$) than STP. Within the group, both STP ($p<0.001$) and IATP ($p<0.001$) showed significant results. The impact of the intervention on whole body fat % between the groups showed that IATP had a significant outcome ($p<0.001$) than STP. Both STP and IATP had significant reduction in body fat (%) from baseline to the 90th day of the intervention

($p < 0.001$). The study's findings show that, on visceral fat IATP had a significant outcome ($p < 0.001$) than STP. Within the group analysis of visceral fat before and after intervention revealed that both groups showed statistical significance ($p < 0.001$). The results of the intervention on body surface area between the groups showed that group IATP had significant changes ($p = 0.005$) than STP. Statistical analysis within the group on body surface area shows that both STP ($p = 0.01$) and IATP ($p = 0.001$) groups showed significant improvement. The effect of the intervention on HbA1c showed a significant difference ($p < 0.001$) in between-group comparison, favoring group IATP. Within the group comparisons, HbA1c before and after intervention showed that there is a significant improvement ($p < 0.001$) in both groups. The impact of interventions between the group on FBS showed a significant difference ($p = 0.02$) with better results in IATP. Within the group, both STP ($p = 0.001$) and IATP ($p < 0.001$) showed significant results. The result of the intervention on PPBG showed that group IATP had significant reduction ($p < 0.001$) than STP when compared between the groups. Within the group, both STP ($p < 0.001$) and IATP ($p < 0.001$) showed significant improvement. The result of the intervention on serum insulin revealed a comparable outcome between the group ($p = 0.168$). Within the group shown that, both STP ($p = 0.001$) and IATP ($p < 0.001$) showed significant improvement. The outcome of the intervention on HOMA IR between the groups showed a significant difference ($p = 0.005$) revealing that IATP had greater improvement. Within the group revealed that, both STP ($p = 0.001$) and IATP

($p < 0.001$) showed significant results. Result of intervention of total cholesterol, when compared between the groups, there are no significant differences ($p = 0.60$). However, within the group, IATP showed significant improvement ($p = 0.01$), whereas STP showed non-significant changes ($p = 0.17$). Result of intervention on HDL and LDL showed non-significant results both between and within the group. The result of intervention on VLDL showed a non-significant difference between the group ($p = 0.57$), however, within the group, IATP showed significant results ($p = 0.01$), whereas STP showed non-significant improvement ($p = 0.08$). In serum triglycerides, when compared between the groups, IATP showed significant changes ($p = 0.004$) than STP. Within the group, both STP ($p = 0.01$) and IATP ($p < 0.001$) had significant effects. The severity decreased from borderline triglyceride level (T: 182 mg/dl) to normal triglyceride level (T: 142 mg/dl) in IATP group. Diabetes Quality Of Life (DQOL) has four domains that include, satisfaction, impact, concern (related to social/vocational) and concern (related to DM). Effect of intervention on satisfaction, impact score showed significant difference ($p < 0.001$) favoring IATP. In concern domain (related to social/vocational), showed comparable result. Overall score demonstrated that there is a large difference between the groups ($p < 0.001$) with better improvement IATP ($p < 0.001$). Comparison of different treatment time points with serum creatinine within the group revealed that both STP and IATP showed significant changes ($p < 0.001$).

- **Discussion**

- Integrative approaches, such as self-management, healing modalities, and lifestyle modifications, are increasingly being researched for their effectiveness in treating various disorders. The advantages of an integrative approach in the treatment of pain, cancer, diverse neurological illnesses, cardiac and other lifestyle disorders etc. are currently being thoroughly researched. Our comprehensive treatment strategy for uncontrolled T2DM in this clinical research involves herbal medicine, diet, and yoga therapy. Herbal remedies have been utilized extensively in the context of complementary and alternative medicine for both specific health issues and overall wellbeing. *Madhumehari ghanavati* has ten herbs. gymnema Sylvestre (Retz.), syzygium cumini L., *triphala* (a blend of *Embllica officinalis* Gaertn, *Terminalia chebula* Retz, *Terminalia belirica* Roxb.), *pterocarpus marsupium* Roxb, *curcuma longa* Linn, *tinospora cordifolia* willd, *Cinnamomum tamala* (Buch, Ham) and *Berberis aristata* DC have *pramehagna* and *medohara* property. Also, following drugs have insulin sensitizing, lipid lowering, anti-hyperglycemic properties. The diet includes foods that are nutrient-dense and energy-boosting rather focusing solely on caloric intake. Ayurveda food works at insulin resistance characteristics, as it contains time restricted eating patterns. Time restricted eating is a pattern of Intermittent Fasting (IF). A recent meta-analysis reviewed of IF diets found that they reduce insulin resistance. Due to the high level of glucose intolerance in the morning we introduced low-carb (LC) breakfasts (using lentils and beans). A

randomized trial evaluated the impact of LC breakfast on blood glucose control in T2DM when compared with low fat content breakfast revealed that HbA1c was reduced after 12 weeks of a LC breakfast. India's super food, millet, is widely consumed locally and is used in all facets of daily life. Millets are high in fiber, satiating, and minimize meal frequency. According to review, it can help manage diabetes due to its high fiber, polyphenol, and antioxidant content. An experiment using diabetic mice to test different diets showed that millet can boost insulin sensitivity and lower blood glucose and lipid levels. The Ayurveda diet emphasizes eating fresh herbal preparations and nuts & seeds. We have the same dietary pattern in Mediterranean-style diet. A higher rate of mediterranean diet observance is linked to 20–23% lower incidence of T2DM due to its antioxidant and anti-inflammatory properties. This diet plan evaluates the consumption of foods that are healthy and appeal to all preferences. The recommended foods are delicious, tasty, and satisfying, which helped to keep the adherence high. Yogic practice for physical activity, breathing techniques, and aspects of relaxation are all incorporated into therapeutic yoga for diabetes. Yoga seeks to achieve a state of physical, emotional, and spiritual well-being by balancing the body, mind, and emotions. Yoga, according to various studies, may reduce insulin resistance. Yoga practitioners reported considerably lower triglyceride levels compared to those who exercised regularly. Surya Namaskar, the basic dynamic yoga position that decreases hip circumference and improves glycemic outcomes, is the foundation of

physical activity-related yoga. A review of prior studies on T2DM analysis included nine eligible studies, of which four showed that yoga with the intervention led to a substantial drop in HbA1c compared to the control group. Yoga significantly affects how well T2DM patients use their glucose. Mechanism of action of IATP could be through insulin sensitizing, antioxidant, and anti-inflammatory action of *Madhumehari ghanavati* with wholesome diet and yoga.

- **Conclusion**

- The Integrated Ayurveda Treatment Protocol (study intervention) in uncontrolled T2DM showed significant efficacy in the primary outcome criteria (HbA1c).
- Study intervention showed better efficacy in other glycaemic parameters (FBG, PPBG).
- Study intervention exhibited improved insulin resistance parameters (Serum insulin and HOMA IR).
- Study intervention led to enhanced quality of life in Uncontrolled T2DM.
- Both the groups experienced mild and small adverse drug reactions (ADR's), with normal creatinine levels indicating safety.
- Study intervention had fewer ADRs, better adherence, and demonstrated an augmentary effect.
- The multimodal treatment approach combining Ayurveda and conventional therapy showed good safety, compliance, and efficacy.
- Integrating Ayurveda treatment alongside conventional therapy could be a beneficial approach for improving glycemic control and overall management of Type 2 DM, potentially leading to better patient outcomes and quality of life.

Keyword: Type 2 Diabetes mellitus, *Madhumeha*, HbA1C, Yoga, Diet

1.2. INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a growing concern worldwide, having reached epidemic proportions in many developing and most developed countries ¹. According to American Diabetes Association (ADA), uncontrolled T2DM is measured as a glycated hemoglobin level (HbA1C) of >7% ².

T2DM is a metabolic condition characterized by insulin resistance and pancreatic β -cell dysfunction caused by uncontrolled hyperglycaemia. There is also a link of inflammation in the pathogenesis of T2DM. The studies looking into the relationship between inflammation and T2DM have gathered enough evidence to support the function of inflammation in the development of insulin resistance and the pathophysiology of T2DM. Clinical and experimental research has shown that adipose tissue is an inflammatory location. The study found that obese mice's adipose tissue produced high levels of TNF- α ³.

Diabetes is a major cause of blindness, kidney failure, heart attacks, stroke, and lower limb amputation⁴. In 2016, an estimated 1.6 million deaths were directly caused by diabetes. Another 2.2 million deaths were attributable to high blood glucose in 2012. Almost half of all deaths attributable to high blood glucose occur before the age of 70 years. World health organization (WHO) estimates that diabetes was the seventh leading cause of death in 2016⁵.

The treatment of T2DM begins with a thorough and interdisciplinary strategy. ADA treatment guidelines emphasize medical nutrition therapy, exercise, pharmaceutical therapy, and the prevention and control of diabetes-related complications.

According to current ADA recommendations, medical nutrition therapy should continue to be part of the treatment strategy once medication is commenced. T2DM medications work by lowering blood glucose levels at different places throughout the body. ADA recommends, metformin is the only medicine shown in randomized controlled trials (RCTs) to reduce mortality and complications. Additional drugs should be introduced in a patient-centred, customized manner, although there is no evidence from RCTs that any of these medications lower the risk of diabetes-related complications, cardiovascular mortality, or all-cause mortality. A 2011 comparative efficacy evaluation found that metformin, second-generation sulfonylureas, thiazolidinediones, and repaglinide (prandin) reduced A1C levels by roughly 1% when used alone, and that combination therapies had an additive effect on A1C levels.

The medications used to manage T2DM have a variety of negative effects. Metformin (biguanides) can cause nausea, diarrhoea, and abdominal bloating. Dipeptidyl-peptidase-4 inhibitors (Alogliptin, Linagliptin, Saxagliptin, and Sitagliptin) can cause headaches and pancreatitis (occasionally). Glucagon-like peptide-1 receptor agonists (albiglutide, dulaglutide, exenatide, and liraglutide) can produce nausea, vomiting, feelings of fullness, weight loss, and hypoglycaemia. Sodium-glucose co-transporter 2 inhibitors (Canagliflozin, Dapagliflozin, and Empagliflozin) increase urinary tract and vaginal infections, low-density lipoprotein cholesterol levels, and weight loss. Sulfonylureas (Glimepiride (Amaryl), Glipizide, and Glyburide) lead to hypoglycaemia and weight gain. Thiazolidinediones (pioglitazone (Actos) and rosiglitazone (Avandia) cause weight gain and swelling⁶.

Insulin therapy should be initiated if a patient fails to achieve glycaemic goals, is used as an initial treatment for T2DM in metabolic decompensation, or in cases of

decompensated renal or hepatic insufficiency, myocardial infarction, stroke, acute severe illness, or major surgery.

Depending on the patient's conditions, either a premixed insulin injection once or twice daily or a basal insulin regimen should be employed. A multi-component insulin regimen should be employed if the glycaemic objective is not met with a basal insulin or premixed insulin regimen. Depending on the patient's condition, combination therapy involving insulin and oral hypoglycaemic medications may be used⁷.

Ayurveda classics describe the etiological factors of *prameha* as sedentary activities, early introduction of milk and its products, animal feed cultivated especially in swampy areas, newly harvested grains, and refined sugars, etc⁸, which have more similarities with the aetiology of T2DM.

Ayurveda classics defines *Prameha* as a set of complex clinical disorders characterized by frequent abnormal micturition, with the etiology involving genetic predisposition as well as improper diet and lifestyle. The clinical conditions described in *prameha* have much in common with diabetes mellitus.

Nidana sevana leads to vitiation of *kapha dosha* in dominance along with other two *doshas* which in turn vitiates *meda* leading to *prameha*. *Purvaroopas* include *shitilangatha* (flabbiness of body), *sada* (malaise), *angagandha* (body odour), *shayyaasana swapna sukha* (liking comfort in lying, sitting, and sleeping), *karapada daha and suptata* (burning & numbness in limbs) etc.^{9,10}.

Clinical features such as *prabhutavilamutrata* (copious urination and turbid urine), *aasyamadhurya* (sweet taste in mouth), *galatalu shosha* (dryness of palate, throat), *tandra* (excessive sleep and continuous drowsiness) etc. are seen¹¹.

Ayurveda recommends different treatment modalities in *prameha* such as *nidana parivarjana* (preventive strategies), *shodhana* (Detoxification), *shamana* (internal medication) and *pathyapathya* (diet and lifestyle restriction). In *prameha*, aggravated *kapha dosha* does vitiation of *medas* (adipose tissue), *mamsa* (muscle tissue) and *kleda* (fluid). Excessively aggravated *medas* leads to *Poorvaroopas* (premonitory symptoms) of *Prameha*. Vitiated *kleda* produces urinary symptoms¹².

Integrated medicine (also known as integrative medicine) is the practice of strategically incorporating parts of complementary and alternative medicine into complete treatment strategies. It emphasizes health and healing over disease and therapy. It views patients as full individuals, with minds, spirits, and bodies, and incorporates these aspects into diagnosis and treatment. It also includes patients and doctors working together to preserve health by focusing on lifestyle issues such as nutrition, exercise, rest and sleep quality, and relationship dynamics¹³.

Integrated medicine through complementary and alternative medicine (CAM) or "complementary health approaches" is a range of different medical and health-care techniques and products that are not now regarded to be part of traditional medicine. The national centre for complementary and integrative health (NCCIH) divides most alternative health therapies into two categories: 1) natural items, such as herbs, vitamins, minerals, and probiotics, which are frequently sold to consumers as dietary supplements; or 2) mind and body practices, which include a wide range of processes or techniques provided or taught by a qualified practitioner or instructor. These

include, yoga, chiropractic and osteopathic manipulation, meditation, massage therapy, acupuncture, relaxation techniques, tai chi, qi gong, healing touch, hypnosis, and movement therapies are some of the options. Other complementary health approaches include traditional healers, Ayurvedic medicine, traditional chinese medicine, homeopathy, and naturopathy¹⁴.

Researchers are currently exploring the potential benefits of integrative approach in a variety of medical conditions including pain management¹⁵, different neurological conditions¹⁶, cancer symptoms and treatment side effects¹⁷, cardiology etc. Integrative approach can be beneficial in T2DM because most of which involve self-management, healing approaches and lifestyle changes. Ayurveda herbs have insulin sensitivity¹⁸, antihyperglycaemic¹⁹, anti-hyper lipidaemic²⁰, antioxidant properties²¹ etc have beneficial effects in T2DM. Ayurveda dietetics have positive outcome in insulin resistance²². Yoga (which includes Surya namaskar, Asanas, pranayama, and meditation) has proven a successful complementary alternative in T2DM ²³.

1.3. BACKGROUND

T2DM is a chronic metabolic condition defined by persistent hyperglycaemia. It could be related to decreased insulin secretion, insulin resistance in the peripheral tissues, or both. According to the International Diabetes Federation (IDF), almost 415 million persons aged 20 to 79 had diabetes mellitus in 2015. Diabetes is becoming a global public health burden, with an additional 200 million cases anticipated by 2040. Chronic hyperglycaemia, in combination with other metabolic abnormalities in patients with diabetes mellitus, can cause damage to various organ systems, leading to the development of disabling and life-threatening health complications, the most prominent of which are microvascular (retinopathy, nephropathy, and neuropathy) and macrovascular complications leading to a 2-fold to 4-fold increased risk of cardiovascular diseases²⁴.

In 2017, around 462 million people were affected by T2DM, accounting for 6.28% of the global population. Diabetes alone causes about 1 million fatalities per year, ranking as the tenth greatest cause of death²⁵. Globally, around 48% cases have uncontrolled T2DM²⁶. Around 25.2 million Indians have uncontrolled T2DM based on impaired glucose tolerance test. This number is expected to increase to 35.7 million by the year 2045²⁷.

Evolving data suggests that, along with defective insulin secretion by pancreatic islet β -cells and tissue insulin resistance, adipokine dysregulation, inflammation, abnormalities in the gut microbiota, immune dysregulation, and inflammation have emerged as important pathophysiological factors. Genetic predisposition and sedentary lifestyle play an important role in the risk of developing T2DM.

T2DM presents acute and chronic complications. Acute complications are diabetic ketoacidosis & diabetic coma, hypoglycaemia, and hyperglycaemia. The chronic complications of T2DM are microangiopathy, diabetic retinopathy, nephropathy, neuropathy, diabetic foot. Additionally, vulnerability to infections, myopathy, osteoporosis, arthropathies and liver damage are often associated with diabetes mellitus. Almost all morbidity in T2DM can end up with cardiovascular diseases such as coronary disease, congestive heart failure and arterial hypertension²⁸.

Existing research on integrated Ayurveda treatment protocol

Elder C et al. conducted a study on complementary and alternative medicine (CAM) to determine the feasibility and clinical impact of a whole-system Ayurvedic intervention for newly diagnosed people with T2DM. Treatment for the experimental group included exercise, an Ayurvedic diet, meditation instruction, and an Ayurvedic herb supplement (MA 471). Control patients attended standard diabetes education classes with primary care clinician follow-up. Clinical outcomes were assessed at 3 and 6 months and included HbA1C, fasting glucose, lipids, blood pressure, and weight. There were statistically significant improvements in the Ayurvedic group for HbA1c ($P = .006$), fasting glucose ($P = .001$), total cholesterol ($P = .05$), low-density lipoprotein (LDL) ($P = .04$), and weight ($P = .035$). Results suggest that the Ayurvedic intervention may benefit patients with higher baseline HbA1c values, warranting further research²⁹.

Purnima Datey et al. conducted a six-month randomized controlled clinical trial (RCT) to see if treatment with fresh herbal juices and yoga can improve the levels of blood glucose and haemoglobin A1c (HbA1c) in people with pre-diabetes. 157 newly diagnosed Type 2 subjects were divided into three groups: (1) *Rasahara*

and *Yoga*, (2) *Yoga*, and (3) no intervention. Fasting blood sugar (FBS) and post prandial blood sugar (PPBS) levels were measured every 2 weeks, and HbA1c and blood lipids were determined pre- and post-intervention. The duration of the intervention is six months. This study proved that the *Yoga* and *Rasahara* groups got beneficial results. Follow-up studies should be carried out to obtain more robust results³⁰.

Hsia SH et al conducted a RCT to see the effect of a standardized Ayurvedic formulation on diabetes control in newly diagnosed T2DM showed Ayurveda formulation decreased the glycemic level and improved lipid homeostasis, while maintaining the other serum biochemical levels to the normal, and therefore it may be useful for the patients in new cases of T2DM.³¹

A study by Rohit Sharma et al. examined the impact of *yoga* therapy on managing non-insulin-dependent diabetes mellitus (NIDDM) and reducing the oral drug dose requirement of *guḍūcī ghana* Tablet. In this study, thirty known NIDDM patients of both genders, who were on *guduchi ghana* (solidified aqueous extract of *Tinospora cordifolia* (Willd.) Miers.) tablets from the past 2 months as Ayurvedic remedy for DM were selected. Along with *guḍūcī ghana* administration, the subjects were instructed to follow yogic procedures including *asanas*, *pranayama*, and *shuddi kriyas* for 8 weeks. Fasting blood sugar (FBS) and post prandial blood sugar (PPBS) levels along with relief in sign and symptoms were assessed at every 2 weeks intervals. The results showed a significant reduction in the dose of *guduchi ghana* tablets and a fall in FBS and PPBS levels after the treatment. The results showed a significant reduction in the oral drug dose requirement³².

A study was conducted by Archana Gupta et al. to assess the clinical effects of dietary interventions and lifestyle modifications in *Madhumeha* (T2DM) patients. The present study was carried out on 56 patients of *Madhumeha* from S.S. Hospital, Banaras Hindu University, Varanasi. A dietary intervention and lifestyle modification schedule was prepared based on Ayurvedic principles, and patients were advised to follow this regimen. Three consecutive follow-ups were done for three months at an interval of one month each. Significant improvement was observed in clinical signs and symptoms, along with plasma glucose and glycosylated haemoglobin (HbA1c) in *Madhumeha* patients after these interventions ($P < 0.001$). Hence, it can be concluded that dietary interventions and lifestyle modifications are two important tools by which adequate glycaemic control can be obtained, especially in newly diagnosed T2DM patients and in patients who are on anti-diabetic medication but are not properly controlled³³.

Stanley H, Hsia et al. carried out a single-centre, randomized, double-blind, placebo-controlled 3-month trial to evaluate the effect of pancreas tonic (an *ayurvedic* herbal supplement) in T2DM inadequately treated with diet, lifestyle, or stable doses of sulfonylureas and/or metformin for at least 3 months. All subjects began a 1-month single-blind placebo run-in phase, followed by randomization in a 2:1 ratio of active treatment: placebo, to 3 months of double-blind treatment with either pancreas tonic or matching placebo (2 capsules 3 times a day). Concurrent oral agents were continued unchanged throughout the study. The primary outcome was the change in HbA1c from baseline to the 90th day. There were no significant treatment-related differences in FBS, lipids, body mass index (BMI), body composition, and blood pressure, insulin sensitivity estimates using the minimal model, glucose and insulin responses to a meal challenge, quality of life, adverse events, or other safety indices

between treatment groups. Pancreas tonic was well tolerated. Treatment with pancreas tonic (2 capsules 3 times per day) for 3 months significantly improved glucose control in T2DM patients with HbA1c levels between 10.0% and 12.0%. This study represents the first properly designed, prospective intervention trial of therapy with an *Ayurvedic* herbal supplement for intermediate-term glucose control in T2DM³⁴.

A study by Harshika Awasthi et al. investigated the effectiveness of a standardized polyherbal formulation containing aqueous extracts from six herbs in patients with T2DM. The study involved 93 newly diagnosed patients who were randomly assigned to groups 1 (received polyherbal capsules at 500 mg/day, up titrated weekly to a maximum of 3 g/day) and 2 (received metformin at 500 mg/day, up titrated weekly to a maximum of 2 g/day). The primary endpoint was the effect on blood glucose and glycosylated haemoglobin levels. The secondary outcome included the effect on lipid levels, liver enzymes, and renal function tests. After 24 weeks, the polyherbal formulation (PHF) treatment group showed a 25.52% and 24.22% decrease in fasting and post-prandial blood glucose, respectively, compared to the metformin treatment group. However, the PHF treatment group showed a more pronounced decrease in total cholesterol levels. The study concluded that daily intake of this PHF decreased glycaemic levels and improved lipid homeostasis while maintaining other serum biochemical levels to normal, making it potentially useful for T2DM patients³⁵.

2. AIM & OBJECTIVES AND HYPOTHESIS

Primary Objective: To evaluate the efficacy of integrated Ayurveda treatment protocol as add-on therapy in patients of uncontrolled T2DM in achieving the glycemic control assessed through HbA1C

Secondary Objective: To compare the effect of integrated Ayurveda treatment protocol and standard treatment regimen intervention on changes in biochemical parameters of T2DM (fasting insulin, HOMA IR, lipid profile) and quality of life.

Hypothesis

Null hypothesis: Integrated Ayurveda treatment protocol which includes Ayurveda drug, diet and yogic intervention given for duration of 90 days is not equivalent to standard treatment protocol in uncontrolled Type 2 Diabetes Mellitus.

Alternate Hypothesis: Integrated Ayurveda treatment protocol which includes Ayurveda drug, diet and yogic intervention given for duration of 90 days is equivalent to standard treatment protocol in uncontrolled Type 2 Diabetes Mellitus.

3. REVIEW OF LITERATURE

3.1. Disease review

Disease review is explained under following sub-headings:

Prameha

- *Nidana panchaka of prameha*
- *Chikitsa of prameha*
- **Review on T2DM Mellitus (T2DM)**

1. *Nidana panchaka of prameha*

a. *Nidana* of *prameha* can be divided into 2 types - *sahaja* (hereditary) and *apathya nimitaja* (acquired). *Apathya Nimitaja* (acquired) is further classified into three types: 1. *Kaphakara* 2. *Pittakara* 3. *Vatakara*³⁶.

i. ***Sahaja***: *Sahaja* or *jatah prameha* indicate involvement of genetic predisposition in the pathophysiology of disease which depends on the *beeja bhaga* dosha or *ahita ahara vihara* of the mother during intrauterine life of a person³⁷. *Acharya Charaka* explains that the main cause of chromosomal damage to the sperm and ovum leading to *prameha* is the excessive consumption of foods with a *madhura rasa* (sweet taste) by the parents³⁸. Additionally, the mother's diet, lifestyle, and psychological state during lactation can also significantly contribute to the susceptibility of infants to *prameha*³⁹.

ii. ***Apathyanimitaja***:⁴⁰ In *apathyanimitaja prameha*, faulty lifestyle, dietary factors, and psychogenic factors are identified as contributors to the development of *prameha*. Depending on the involvement of specific doshas, the *samhitas* highlight the specific *nidana* (causes) for different

types of *prameha*. In the initial stages of *prameha*, there is an excess of *kapha dosha*, which disrupts the balance of *meda* (fat) and *kleda* (body fluid), leading to the onset of *kaphaja prameha*. As the condition progresses, there is a further depletion (*kshaya*) of *kapha*, and *pitta dosha* becomes predominant. *Pitta* then disturbs the *rakta*, resulting in *pittaja prameha*.

Table No.1: Showing the *aharaja nidana* of *prameha*

<i>Nidana</i>	C.S	S. S	A.H	M.N	B. P
<i>Nava Dhanya</i> (New cereals)	+	-	+	+	-
<i>Sura</i> (Wine)	+	-	+	-	-
<i>Anupa Gramya Udaka</i> <i>Mamsa</i> (meat of aquatic Animal)	+	-	+	+	+
<i>Ikshu</i> (sugarcane products)	+	-	+	+	+
<i>Ksheera</i> (milk Products)	+	-	+	+	+
<i>Dadhi</i> (curd)	+	-	+	+	+
<i>Hayanaka</i> (<i>Oriza sativa</i>), <i>Yavak</i> (<i>Hordeum vulgare</i>)	+	-	-	-	-
<i>Harenu</i> (<i>pizum sativa</i>), <i>Masha</i> (<i>vigna mungo</i>)	+	-	-	-	-

Table No.2: Viharaj nidana of prameha

Nidana	C.S	S. S	A.H	M.N	B. P
<i>Aasya sukha</i> (sedentary lifestyle)	+	+	+	+	+
<i>Swapna sukha</i> (Bed rest)	+	+	+	+	+
<i>Divaswapna</i> (Day sleep)	+	+	-	-	-
<i>Avyayama</i> (No exercise)	+	+	-	-	-
<i>Atapa sevana, agni santapa</i> (Exposure to fire)	+	-	-	-	-
<i>Ajeerna bhojana</i> (food taken during indigestion) <i>Anashana</i> (fasting)	+	-	-	-	-
<i>Vegadharana</i> (holding natural urges), <i>Abhigata</i> (trauma)	+	-	-	-	-

2. Purvarooopa and Roopa

In *Ayurveda* classics both *brahatrayi* and *laghutrayi* had explained *Purvarooopa* (premonitory symptoms) and *Roopa* (Symptoms) of *Prameha*. Various symptoms had been mentioned such as *kara-pada daha* (burning sensation in both the hands and feet), *aasya madhurya* (a sweet taste in the mouth), *pipasa* (feeling thirsty), *mukha-talu-kantha shosha* (dryness in the oral cavity), *visrashareera gandha* (a foul

smell coming from the body), *jatilabhava keshanam* (tangled hair), *tandra* (drowsiness), *shat pipilika mutravisarana* (insects and ants being attracted to the body and urine) , *kayamalayukta* (waste adhering to body orifices), *kara-pada suptata* (numbness in both the hands and feet), *anga daha* (a burning sensation in the body), *anga suptata* (numbness of the body), *alasya* (laziness), *kaya upadeha* (afflicting body), *nidra* (feeling sleepy), *nakha vridhhi* (rapid growth of nails) , *shayya asana-swapna sukha* (feeling a sense of laziness and preference for lying down, sitting, and sleeping), a sensation as if the cardiac region is covered with foreign material.

Table No.3: Views of *purvaroop* & *roop* of *prameha* in *Brihatrayi*'s

Sr. No	Symptoms	<i>Charaka</i> ⁴¹	<i>Sushruta</i> ⁴²	<i>Ashtanga Hridaya</i> ⁴³	<i>Ashtanga Sangraha</i> ⁴⁴
1	<i>Paadadaha</i> (burning sensation in feet)	+	+	+	+
2	<i>Nakha kesha aashuvridhhi</i> (Rapid growth of nails and hairs)	+	+	+	
3	<i>Gatra dourgandhyam</i> (Foul smelling of body)	+	+	-	+
4	<i>Kesha jatilata</i> (Matting and nasty appearance of hair)	+	+	-	+
5	<i>Tandra</i> (drowsiness)	+	+	-	+
6	Excreta over body	+	+	-	+
7	<i>Asyamadhuryam</i>	+	-	+	+

	(sweetness of mouth)				
8	<i>Asyashosha</i> (dryness of oral cavity)	+	-	+	+
9	<i>Adhika trishna</i> (excessive thirst)	+	-	+	+
10	<i>Sheetabhi kamata</i> (desire for cold Things)	+	-	+	-
11	<i>Mootrabhisaranam pippilikabihi</i> (ants attracted to urine).	+	-	+	-

Table No.4: Most Common *poorvaroopas* & *roopa* of *prameha* in other classics

Symptom	C.S	S. S	A.H	A. S	M.N ⁴⁵	B. P ⁴⁶	Y. R ⁴⁷	V.S ⁴⁸
Daha (Burning Sensation in feet)	+	+	+	+	+	+	+	+
Mukha madhurya (sweetness in mouth)	+	-	+	+	+	+	+	+
Trishna (excessive thirst)	+	-	+	+	-	-	-	-

3. Classification of prameha:

All *Brahatrays* had classified *prameha* based on different classifications such as *dosha*, *nidana*, *samprapti*, *chikitsa perspective* and *sadhyasadhyata*.

Table No.5: Classification of prameha

Sr. No	Classification Factor	Types
1	<i>Dosha</i>	1. <i>Vataj</i> - 4 types 2. <i>Pittaj</i> - 6 types 3. <i>Kaphaj</i> - 10 types
2	<i>Nidana</i> (etiology)	1. <i>Sahaja and Apathyanimitaj</i> 2. <i>Santarpanjanya and Apatarpanjanya</i> 3. <i>Prakriti Prabhava & Swakrita</i>
3	<i>Samprapti</i> (pathogenesis)	1. <i>Avaranajanya</i> 2. <i>Dhatukshyajanya</i>
4	<i>Prakriti</i>	1. <i>Sthoola Pramehi</i> 2. <i>Krishha Pramehi</i>
5	<i>Sadhya/Asadhyata</i> (good prognosis/incurable)	1. <i>Sadhya</i> 2. <i>Yapya</i> 3. <i>Asadhya</i>

Table no.6: Types of prameha as per brahatrayi^{49,50,51}

<i>Kaphaja prameha</i>			<i>Pittaja prameha</i>			<i>Vataja prameha</i>		
<i>Charaka</i>	<i>Sushruta</i>	<i>Vagbhata</i>	<i>Charaka</i>	<i>Sushruta</i>	<i>Vagbhata</i>	<i>Charaka</i>	<i>Sushruta</i>	<i>Vagbhata</i>
<i>Udakameha</i>	<i>Udakameha</i>	<i>Udakameha</i>	<i>Ksharameha</i>	<i>Ksharameha</i>	<i>Ksharameha</i>	<i>Vasameha</i>	<i>Vasameha</i>	<i>Vasameha</i>
<i>Ikshuvalikameha</i>	<i>Ikshumeha</i>	<i>Ikshumeha</i>	<i>Neelameha</i>	<i>Neelameha</i>	<i>Neelameha</i>	<i>Majjameha</i>	<i>Sarpimaha</i>	<i>Majjameha</i>
<i>Saandrameha</i>	<i>Saandrameha</i>	<i>Saandrameha</i>	<i>Kalameha</i>	<i>Amlameha</i>	<i>Kalameha</i>	<i>Hastimeha</i>	<i>Hastimeha</i>	<i>Hastimeha</i>
<i>Sandraprasada</i>	<i>Surameha</i>	<i>Surameha</i>	<i>Haridrimeha</i>	<i>Haridrimeha</i>	<i>Haridrimeha</i>	<i>Madhumeha</i>	<i>Kshoudrameha</i>	<i>Madhumeha</i>
<i>Shuklameha</i>	<i>Pishtameha</i>	<i>Pishtameha</i>	<i>Manjishtha</i>	<i>Manjishthameha</i>	<i>Manjishthameha</i>			
<i>Shukrameha</i>	<i>Shukrameha</i>	<i>Shukrameha</i>	<i>Lohitameha</i>	<i>Raktameha</i>	<i>Raktameha</i>			
<i>Sikatameha</i>	<i>Sikatameha</i>	<i>Sikatameha</i>						
<i>Sheetameha</i>	<i>Lavan</i>	<i>Sheeta</i>						

<i>eha</i>	<i>ameha</i>	<i>meha</i>						
<i>Shanair</i> <i>meha</i>	<i>Shanai</i> <i>rmeha</i>	<i>Shanai</i> <i>rmeha</i>						
<i>Alalame</i> <i>ha</i>	<i>Phena</i> <i>meha</i>	<i>Lalam</i> <i>eha</i>						

- **Types of *Prameha* and their clinical features (with correlations)**

- **Kaphaja *Prameha***

- *Udakameha* (hydruria) - Features of urine in udakameha include urine discharge that is clear, copious, white, and cold, an absence of odor, little turbidity and greasiness, and resemblance to pure water.
 - *Ikshumeha* (glycosuria) - Urine discharge turns sweet like the juice of sugarcane, cold slightly saline, and turbid
 - *Sandrameha* (chyluria) - If kept undisturbed for some time in a pot assumes thickness (increase in viscosity)
 - *Sandrapsadameha* (Belluria) - The urine of the patient becomes partly viscous and partly clear when kept overnight.
 - *Surameha* - Resembles alcoholic bevarages prepared with flour with clear fluid and sediments at the bottom and top.
 - *Pishtameha/Shuklameha* - Appears thick as dough mixed with flour and is white in colour. The patient experiences horripilation

- *Shukrameha* (spermaturia)- Urine resembles semen or even it might be mixed with the semen.
- *Sikatameha* (Graveluria)- Urine contains small particles resembling sand, where the vitiated doshas comes through urine in the form of small and hard things
- *Sitameha* (Phosphaturia) - Urine is copious, patient gets frequent micturition which is exceedingly sweet in taste and very cold to touch.
- *Sanairmeha* - Urine is discharged frequently but with difficulty and slowly
- *Lalameha/Alalameha* (Pyuria) - Urine is slime like phlegm and is full of threads.
- Pittaja Prameha
 - *Ksharameha* (Alkalinuria) - Patient passes the Urine resembling alkali in smell, colour, taste and touch.
 - *Neelameha* (Indigouria) - Patient passes urine having sour taste and colour like that of feather of casa bird
 - *Kaalameha* (Melanuria) - Patient passes large quantity of black urine
 - *Raktameha* (Hematuria) - Patient passes urine having red colour, saline taste and smell like that of flesh
 - *Manjishtameha* (Hemoglobinuria) - Patient frequently passes urine having the smell like that of raw flesh and colour like that of Juice of Manjishta

- *Haridrameha* (Urobilinuria) - Patient passes urine having pungent taste and colour like that of juice of Haridra. Patient experience burning sensation during micturition
- Vataja Prameha –
 - *Vasameha* (Lipuria) - This condition is incurable and caused by aggravation of vata, the patient frequently passes urine mixed with vasa or having the appearance of vasa. The aggravated vata in this type of body spreads along with vata enters channels carrying urine leading to manifestation of vasameha
 - *Majjameha* (Myelouria) - The patient frequently passes urine mixed with majja
 - *Hastimeha* (Diabetes insipidus) - Patient passes large quantity of urine frequently like an elephant gone amuck.
 - *Madhumeha* (Diabetes Mellitus) - Patient passes urine sweet and astringent in taste, pale in colour and ununctuous.

4. Samprapti:

Samanya Samprapti of Prameha⁵²

It can be defined on the premise of *Shatakriyakala*.

- a) *Sanchaya*:** The *nidana sevana*, results in accumulation of *kapha dosha*. It is important to note that the accumulated *kapha dosha* in this case is of high quantity, characterized by its *bahudravatva* (excessive fluidity). In its *prakritavastha* (natural state), *kapha* remains in a *baddha shape* (stable, solid form). However, due to the influence of the lifestyle factors, its original stable

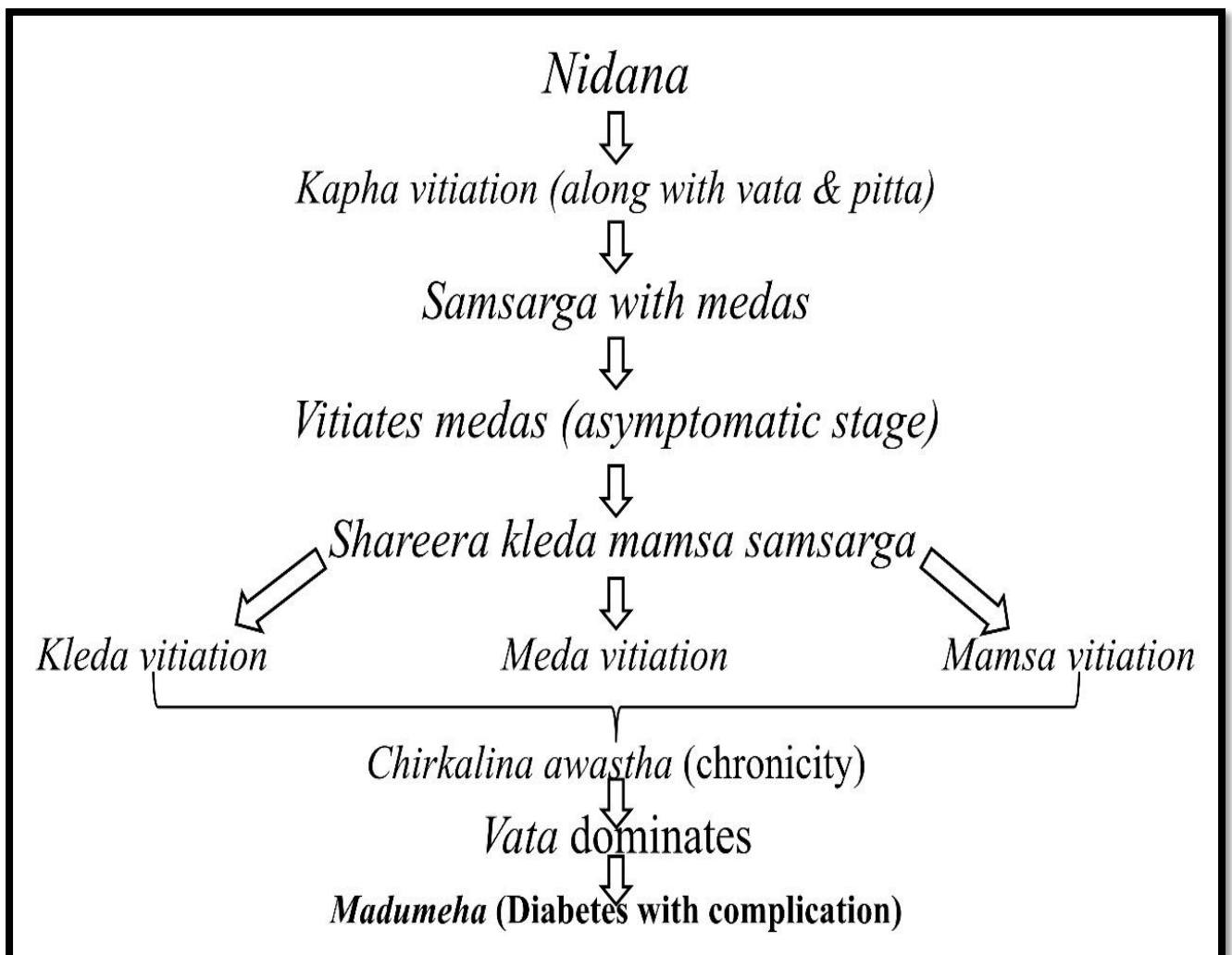
form undergoes a transformation into a more *dravatva* (liquid form), and (*bahudravatva*) that too in larger quantities.⁵³

- b) *Prakopa*:** The 3 elements i.e *Nidana*, *dosha* and *dushya* get blended collectively and they cause *prakopa* of *bahudrava kapha* hastily and *prameha* in future⁵². If person indulge in *nidanas*, had *kaphaja prakriti* and who're having genetic predisposition for *prameha*.
- c) *Prasara*:** At this stage, the aggravated *kapha dosha* spreads throughout the body due to the *shaithilya* (weakening) of the physical tissues. The weakening of the physical tissues is considered one of the favorable factors contributing to the progression of the dosha imbalance as part of the overall *nidana* (causative factors).
- d) *Sthana Samshraya*:** *Vikrita kapha*, due to its similar properties, has an affinity towards *bahu-abaddha meda* (excessive adipose tissue) and gets lodged there. When *vikruta kapha* combines with *bahu-abaddha meda*⁵⁴, it causes an imbalance, affecting other important bodily tissues such as *sharira kleda* (bodily fluids) and *mamsa* (muscles), which are already present in large amounts prior to the *kapha* imbalance. The provoked *kapha*, along with vitiated *meda*, combines with *sharira kleda* or *mamsa*, or both. This stage is crucial as it manifests prodromal symptoms of the disorder. Early diagnosis at this stage is important to prevent further progression of the disease for better prognosis.⁵²
- e) *Vyakta*:**⁵² At this stage of *vyaktavasta* (manifestation stage), various manifestations occur. One manifestation is *mutravaha srotodushti*, which occurs when the vitiated *kapha* and *meda* met with and disrupt the balance of *sharira kleda*, leading to urinary system disorders. The vitiated *kapha* settles

in the *bastimukha* (bladder region), which is already affected by vitiated *meda* and *kleda*, resulting in the development of the disorder *prameha*. Another manifestation is *puti mamsa pidika*, which occurs due to the vitiation of *mamsa dhatu* (muscle tissue). The vitiated *kapha* and *meda* combine with *mamsa dhatu*, leading to the formation of painful swellings. These manifestations of *kleda* and *mamsa dushti* can occur simultaneously or in stages.

- f) **Bheda:**⁵² During this stage, various complications of the disorder arise, leading to *prameha pidakas*.

Fig No.4: *Prameha samprapti*



Samprapti ghatakas of Prameha:^{55,56,57}

Dosha: Tridosha [Kapha pradhana]

Dushya: Rasa, Rakta, Mamsa, Meda, Majja, Shukra, Vasa, Oja, Lasika, Kleda and Sweda

Srotodushti: Atipravarthi of dushyas through the mutra.

Agni: Vaishamya of respective Agnis

Ama: Jataragnimandya and dhatvagnimandya- medogata ama

Adhisthana: Mutravaha srotas

Udbhavasthana: Amapakvashaya

Bhedavastha: Occurrence of upadravas such as puti mamsa and prameha pidika etc.

Nature: Chirakari

○ **Nature of dosha and dushya's**

○ **Nature of Dosha:**

○ *Kapha dosha*

○ *Bahudrava shleshma* (there is increase in *drava guna* of *kapha*)

○ *Snigdha* (unctuous) and *Guru* (heavy) *guna*

○ Due to this, there is accumulation of *meda dhatu* (fat tissue), a common feature in *Prameha*.

○ *Sthira* (stable) and *Manda* (slow): Causes sluggishness in metabolic processes, leading to *dhatu dushti* (vitiation of tissues).

○ Nature of *dushya*

○ *Meda Dhatu* (Fat Tissue):

- *Meda* is a key *dushya* in *pramehaha* and closely linked to *Kapha* due to their similar qualities and causative factors in *prameha*.
- *Bahu* (Excess): *Meda* increases in quantity and accumulates in an immature form (*aparipakva*), obstructing pathways and aggravating *vata*. This stimulates appetite, leading to overeating and further *meda* accumulation, ultimately disrupting other *dhatu*s.
 - *Abaddha* (loosely bonded): The quality of *meda* deteriorates, becoming flabby and causing *shaithilya* (looseness), which correlates with increased free fatty acids (FFAs) and heaviness in the body.
- *Mamsa Dhatu* (Muscle Tissue):
 - *Mamsa* loses its normal consistency, leading to *shaithilya* (looseness) and allowing space for fatty deposits. This results in conditions like *putimamsapidika* (foul-smelling pustules).
- *Majja Dhatu* (Bone marrow and nerve Tissue):
 - Although *majja* is less affected, vitiated *vata* causes its depletion, leading to symptoms like *netra gaurava* (heaviness in the eyes) and *anga gaurava* (heaviness in the body).
- *Rasa Dhatu* (Plasma and Lymph):

- *Rasa*, as the seat of *kapha*, becomes vitiated due to *kapha* imbalance. Symptoms include *alasya* (lethargy), *gaurava* (heaviness), *Karshya* (emaciation).
- *Rakta Dhatu* (Blood):
 - *Rakta* is mainly involved in *Pittaja prameha*, presenting symptoms like *daha* (burning sensation), *pidika* (pustules), *vidradhi* (abscesses).
- *Shukra Dhatu* (Reproductive Tissue):
 - *Shukra* vitiation leads to *daurbalya* (weakness), *kruchravayavayata* (difficulty during intercourse). Vata-induced depletion of *shukra* results in conditions like *shukrameha* (diabetes with seminal discharge).
- *Ojas* (Vital Essence):
 - *Ojas* is mainly associated with *Vataja Prameha*, manifesting as *Ojomeha* (a subtype of *Madhumeha*). Symptoms of *ojakshaya* include *gurugatrata* (body heaviness), *nidra* (excess sleep), *tandra* (drowsiness), *daurbalya* (weakness).
- *Kleda* (Moisture):
 - *Kleda* signifies moisture and dampness, physiologically managed by *mutra* (urine) and *sweda* (sweat). When vitiated, *kleda* affects these processes, leading to *prabhuta mutrata* (polyuria), *swedavridhi* (excessive sweating), *shaithilya* (weakness), *daurgandhya* (foul odor), *avilamutrata* (turbid urine). Glycosuria in

diabetes leads to osmotic diuresis, causing water and electrolyte loss, while excessive sweating results in further electrolyte imbalance.

- *Vasa* (Fat):
 - *Vasa*, the unctuous component of *mamsa dhatu*, is affected in *vasameha*, a subtype of *vataja Prameha*. Modern understanding links *vasa* with adipose tissue dysfunction, insulin resistance, and impaired glucose metabolism due to elevated free fatty acids and pro-inflammatory factors.
- *Lasika* (Lymph):
 - *Lasika*, a fluid located just beneath the skin, is vitiated in *hastimeha* (a subtype of *Vataja Prameha*). Vitiating *vata* disturbs *lasika*, leading to *lasikameha*.
- *Sweda* (Sweat):
 - *Sweda*, associated with *meda* and *kleda*, becomes a *dushya* in *Madhumeha*. Vitiating causes symptoms like *swedavridhi* (excessive sweating), *daurgandhya* (foul odor), *picchilagatrata* (slimy sensation on the body). *Vagbhata* mentions that in *Madhumeha*, sweat acquires a sweet nature (*madhura sweda*).
- *Prameha* is primarily a *Kapha-pradhana Vyadhi* (disease dominated by *Kapha*), and the involvement of *Dushyas* (vitiating bodily tissues) reflects the dominance of *Kapha*. The characteristic feature of *Shaithilya* (*laxity*) in *Prameha* can be

attributed to the nature of *Asthira Dhatus* (unstable tissues). However, *Asthi Dhātu* (bone tissue), being a *Sthira Dhātu* (stable tissue) and predominantly associated with *Vata Dosha*, is generally not involved in the pathogenesis of *Prameha*.⁵⁸

- ***Upadrava's of Prameha/Madhumeha [As per Sushruta Samhita]***
 - ***Upadrava's of Kaphaja prameha***
 - Makshikaupasrapna (flies, insects falling on body), alasaya (lethargy), mamasaupachaya (increase of mamsa), pratishyaya (mucus discharge from nose), Shaithilya, arochaka (tastelessness), avipaka (indigestion), kaphapraseka (salivation), chardhi (vomiting), atinidra (excessive sleep), kasa (cough), shwasa (breathlessness).
 - ***Upadravas of Pittaja prameha***
 - Bastibedha (breaking type of pain in basti), Medrathoda (needling type of pain in pens), hridshoola (pain in cardiac region), jwara, atisara (diarrhoea), arochaka, chardi, paridhoomayana (fuming sensation), daha (burning sensation), moorcha (loose consciousness), pipasa(thirst), nidranasha (loss of sleep), panduroga (pallor), peetavinmootranetratva (yellowish urine and eyes).
 - ***Upadravas of Vataja prameha***
 - Hridgraha (impaired state of heart), Loulya (restlessness), anidra, stambha (stiffness), kampa

(tremor), shoola (pain), baddhapurishatva (constipation).⁵⁹

○ **Prognosis of Prameha**

- According to Acharya Vagbhata, if *prameha* initially presents with premonitory signs and is caused by a combination of *pitta* and *kapha* doshas but gradually progresses to *vataja* Prameha, it is considered *asadhya* (incurable). **Pittaja Prameha** is generally considered *yapya* (manageable). However, if the meda dhatu is not significantly vitiated, *pittaja prameha* can be classified as *sadhya* (curable). **Kaphaja Prameha** is considered *sadhya* and can be effectively managed with appropriate treatment.
- According to Acharya Sushruta, a person with prameha who is afflicted with pidikas (lesions) and associated with upadravas (complications) is considered *asadhya* (incurable). As per the commentary of Dalhana, *sahaja* Prameha (congenital diabetes) is deemed as *asadhya* (incurable), *Pittaja prameha* is considered *asadhyatara* (more difficult to treat), while *vataja prameha* is said to be even more difficult to treat than *pittaja prameha*.
- According to acharya charaka, *poorvaroopayukta kaphapittaja prameha*, which gradually progresses to *vataja prameha*, is considered *asadhya* (incurable). *Pittaja prameha* is regarded as *yapya* (manageable), but

it becomes sadhya (curable) if the vitiation of meda dhatu is minimal. Both jataprimeha and madhumeha are categorized as asadhya (incurable).⁶⁰

Chikitsa of Prameha:

a. Nidana Pravirajana

b. Shodhana

c. Shamana

d. Rasayana

e. Pathyapathya

a) Nidana Parivarjana

Avoidance of etiological factors [Both *aharaja* and *vxiharaja* factors]

b) Shodhana chikitsa

In Ayurveda classics, as per patients *bala*, *prakrati* and *vyadhi avastha*, *shodhana* has been mentioned.

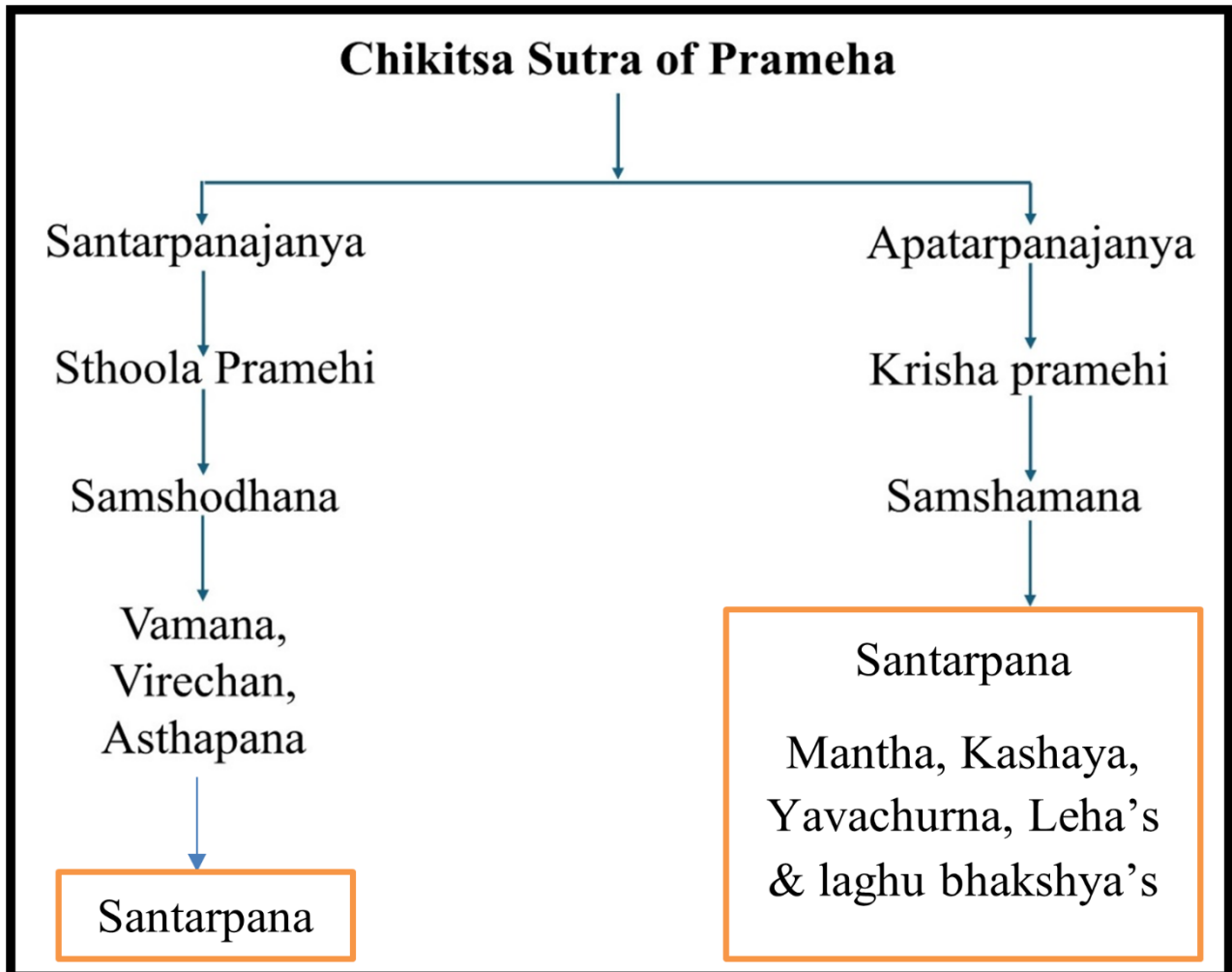
Brahatrayee's view on Shodhana in Prameha

○ ***Charaka Samhita***

- *Shodhana (cleansing therapy)* is recommended for individuals with *sthoola (obesity)* and *balavan (strong)* constitutions.
- Post *shodhana chikitsa*, *santarpana* (nourishing therapy) is essential to prevent complications such as *gulma* (abdominal masses), *kshaya* (wasting), *bastishoola* (bladder pain), and *mootragraha* (urinary retention).

- *Malashodhaka dravyas* should be utilized as per the substances outlined in the *kalpa sthana*.
 - In *Kaphaja prameha*, the primary treatment involves *vamana* (emesis) and *langhana* (lightening therapies).
 - For *Pittaja Prameha*, *virechana* (purgation) is the recommended therapy.
 - In previous commentary, though *apatarpana* (depleting therapy) is contradictory, one more context, *acharya's* advises for *apatarpana* to get the normal state of *meda*, *kleda* and *kapha*. As per *acharya charaka*, *Shareerika kleda, meda, kaphavridhi - apatarpana chikitsa is indicated*.⁶¹
- **Sushruta Samhita**
- *Apatarpana* line of management in *apatya nimittaja prameha* or *sthoola prameha* where *apatya ahara vihara* is the reason. After *apatarpana*, *langhana*, *shodhana*, *vyayama* are included.
 - Post *virechana*, *asthapana basti* can be planned with - *Surasadi gana kashaya*, *shunti*, *devadaru*, *Nagarmotha*, *saindhava*, *madhu*.
 - After *shodhana*, five yogas are advised which can be administered in all type of *prameha*. They include
 - *Amlaki rasa-4 pala + Haridra-1 karsha + Madhu-1 karsha*
 - *Kashaya of triphala, vishala, devadaru, musta*
 - *Kalka of shaala, kampillaka, mushkaka with madhu, amalaka rasa and haridra.*
 - *Kalka of flowers of kutaja, kapitta, rohitaka, vibhitaka, saptaparna with madhu, amlaki swarasa and haridra.*

- *Kashaya* of *Panchanga*'s of nimba, aragwada, saptaparna, murva, kutaja, somavraksha and palasha.
- In *sahaja prameha*, if patient is *weak*, dry, who eats less, has more thirst, who is more active, then *pana* and *bhojana* should include,
 - *Ksoudra*, *kapitta* and *maricha*.
 - *Hingu saindava yukta yusha* processed with *sarshapa* and *rajika kalka*.
 - *Pana* and *bhojana* which is desired by the patient, which is not antagonistic to *prameha* should be administered.
 - *Krishna*(weak) constituent *prameha* person should always be protected.⁶²
- ***Ashtanga Hridaya***
 - In *balavan pramehi*, first line of management would be *Vamana/virechana*, where *snehana* to be done with *sarshapa taila*, *nimba taila*, *danti taila*, *karanja taila*, *trikantakadi taila*.
 - After this, *niruha basti* can be planned with *surasadi gana kashaya* and *shunti*, *devadaru*, *nagarmotha*, *saindhava* and *madhu*.
 - If patient is having the complaints of *daha*, then this *asthapana basti* can be planned with *nyagrodadi gana kashaya* without *Sneha*.
 - In case of *poorvaroop* of *prameha pidika*, *teekshna shodhana* with *ksheerevrikshambu*, *bastamootra* (goats' urine) because *mridu shodhana* does not produce the desired effect in *pramehi*.⁶³

Fig.02: Showing the *Chikitsa sutra* of *Prameha*

c) *Shaman and Rasayana aushadi in prameha:*

➤ *Charaka Samhita*⁶⁴

1. *Swarasa*

- a. *Triphala swarasa*
- b. *Amalaki swarasa with haridra chrurna and madhu.*

2. *Kwatha*

- a. *Daruharidra, devdaru, triphala, musta Kwath with madhu.*
- b. *Haritaki, kataphala, musta, lodhra with madhu*

- c. *Patha, vidanga, arjuna, dhanvaya with madhu*
- d. *Haridra, daruharidra, vidanga, tagara with madhu*
- e. *Kadambatwaka, shalatawaka, arjunatwaka, ajwayana with madhu*
- f. *Triphala, vishala, musta, devdaru kwatha*
- g. *Daruharidra, vidanga, khadira, dhava with madhu*
- h. *Devdaru, kustha, aguru, chandana with madhu*
- i. *Daruharidra, agnimantha, patha, triphala with madhu*
- j. *Patha, murva, gokshura with madhu*
- k. *Yavani, kaasha, haritaki with madhu*
- l. *Guduchi, chavya, chitaka, haritaki, saptaparna with madhu*
- m. *Usheera, lodhra, arjuna, chandana kwatha*
- n. *Patola, nimba, amalaka, guduchi kwatha*
- o. *Musta, haritaki, padmaka, vrikshaka kwatha*
- p. *Lodhra, sungandhbala, kaliyaka, dhataki kwath*
- q. *Nimba, arjuna, amaratka, Nisha, Utpala kwath*
- r. *Shirisha, sarja, arjuna, nagkesara kwatha*
- s. *Priyangu, padma, utpala, kinshuka kwatha*
- t. *Ashwaatha, patha, asana, vetasa kwatha*
- u. *Daruharidra, Utpala, musta kwatha*
- v. *Phalatrikadi kwatha*

3. Churna

- a. *Kampillaka+saptaparna+shala+vibhitaki+rohitaka+kutaja+kapitha
pushpa churna with madhu*

4. Sneha

- a. *Trikantakadi Sneha*

5. Asava, Arishta

- a. *Lodhrasava (madhvasava)*
- b. *Dantyasava*
- c. *Bhallatakasava*

➤ **Sushruta Samhita⁶⁵**

1. Kashaya

- a. *Triphala, vishala, musta, devdaru kwatha*
- b. *Nimba, argavadha, saptaparna, murva, kutaja, somavriksha, palasha, Paarijata Kashaya*
- c. *Vaijayanti Kashaya*
- d. *Nimba Kashaya*
- e. *Chitraka Kashaya*
- f. *Khadira Kashaya*
- g. *Patha, aguru, haridra Kashaya*
- h. *Haridra, Daruharidra Kashaya*
- i. *Saptaparna Kashaya*
- j. *Durva, shaival, plava, hath (jalakumbhika), karanj, kaseruka Kashaya*
- k. *Arjuna, chandana Kashaya*
- l. *Triphala, aaragwadha, mridvika kashaya*
- m. *Ashwatha kashaya and shalsaradi kashaya*
- n. *Aaragvadha kashaya*
- o. *Nayagrodhadi kashaya*
- p. *Triphala kashaya*
- q. *Manjistha, chandana kashaya*

- r. Guduchi, tindukasthi, kashmarya, kharjura kashaya
- s. Guduchi, chitraka kashaya with kustha, kutaja, patha, hingu, rohinikalka
- t. Agnimantha, sinshapa Kashaya
- u. Khadira, kramuka Kashaya
- v. Tinduka, kapitha, shirisha, palasha, patha, murva, dusparsha Kashaya
- w. Asanasara kashaya

Ingredients of Phalatrikadi Kashaya

Prepare a kwatha using *triphala*, *daruharidra*, *vishala* (*indrayava*), and *mustaka*. After preparation, add *haridra* and *madhu* (honey). This formulation is advised for all types of Prameha.⁶⁴

2. Asava

- a. Patha, haritaki, chitraka Asava with madhu

➤ **Ashtanga hridaya**⁶⁶

1. Swarasa

- a. Amalaki, guduchi

2. Sneha

- a. Dhanwantara ghrita

3. Rasayana

- a. Shilajatu rasayana
- b. Ayaskriti

➤ **Sahasrayoga**⁵⁷

1. Kashaya

- a. Vasadi kashaya*
- b. Avartakyadi kashaya*
- c. Kataka Khadiradi kashaya*
- d. Nishakatakadi kashaya*
- e. Darvi Kapithanirysadi kashaya*
- f. Vidangarajanyadi kashaya*
- g. Mudgadi kashaya*
- h. Palashapushpa kashaya*

2. Churna

- a. Khandasama churna*
- b. Pathadi churna*
- c. Akulikatakadi churna*

3. Asava-arishta

- a. Dashmoolarishta*
- b. Devdarvarishta*

4. Rasayana

- a. Agastya rasayana*

5. Guggulu

- a. Kaishor guggulu*
- b. Amrita guggulu*

○ **Review on *Madhumeha* and *chikitsa***

- According to *Ashtanga Hridaya*, if any type of *Prameha* is not treated promptly, it eventually progresses to *Madhumeha*. In this condition, the urine acquires a taste like *madhu* (honey), and the entire body exhibits a *madhura* (sweetness) in nature.⁶⁷
- *Acharya Sushruta* has elaborated on the treatment of *Madhumeha* in a dedicated chapter called *Madhumeha chikitsa cdhyaya*. *Sushruta* has specifically emphasized the use of *Shilajatu* in *tula pramana* (a specific dosage). Additionally, he mentioned the therapeutic application of *Tuvaraka* and *Makshika Rasayana Kalpa*.⁶⁸
 - *Shamana chikitsa* in *Madhumeha*
 - *Shilajatu prayoga*
 - *Swarna makshika prayoga*
 - *Tuvaraka Rasayana kalpa*
 - *Dhanvantara ghruta*

○ ***Pathya* and *Apathya* in *prameha***

Table no.7 Showing *Pathya ahara* in *prameha*.^{69,70,71.}

<i>Varga</i>	<i>Ahara</i>
<i>Shooka dhanya</i> (grains)	<i>Yava</i> (<i>Hordeum vulgare</i>), <i>Truna dhanya</i> (the group of grains produced by grass like plants), <i>Godhuma</i> (<i>Triticum aestivum</i>), <i>Kodrava</i> (<i>Paspalum scrobiculatum</i>), <i>Uddalaka</i> (<i>Cordia dichotoma</i>), <i>Shyamaka</i> (<i>Panicum Frumentaceum</i>), <i>Shastika Shali</i> (<i>Oryza sativa</i>) these must not be newly harvested
<i>Shami dhanya</i> (Legumes)	<i>Chanaka</i> (<i>Cicer arietinum</i>), <i>Arahar</i> (<i>Cajanus cajan</i>), <i>Kulattha</i> (<i>Dolichos biflorus</i>), <i>Mugdha</i> (<i>Vigna radiata</i>), <i>Thuvar</i> (<i>Macrotyloma uniflorum</i>)

<i>Mamsa</i> (Nonveg)	<i>Jangala mamsa</i> which is fatless e.g., <i>Mriga</i> . <i>Dviya Mamsa</i> which is <i>Jangala</i> in origin. <i>Vishkira</i> (gallinaceous birds) and <i>Pratuda Mamsa</i> (pucker birds). These <i>Mamsa</i> must be <i>Shulya</i> , roasted with the help of <i>Shulya</i> (Tandoor)
Milk preparations	<i>Takra</i> (butter milk)
<i>Pana</i> (Drinks)	<i>Madhuudaka</i> (water mixed with honey), <i>Sarodaka</i> (water boiled with the heartwood of <i>Khadira</i>), <i>Kushodaka</i> (water boiled with <i>Kusha</i>), <i>Triphala rasa</i> (juice of <i>Terminalia chebula</i> Linn, <i>Terminalia bellerica</i> Roxb., <i>Embelica officinalis</i>), <i>Sidhu</i> (a type of wine), <i>Madhuvika</i> (type of wine), <i>Madhuudaka</i> (honey water)
Fats and oils	<i>Sarshapa</i> (<i>Brassica campestris</i>), <i>Atasi</i> (<i>Linum usitatissimum</i>), <i>Danti</i> (<i>Baliospermum montanum</i>), <i>Ingudi</i> (<i>Balanites aegyptiaca</i>) <i>taila</i> , <i>Aja mamsa</i> (goat meat)
Fruits	<i>Bilva</i> (<i>Aegle Marmelos</i>), <i>Beejapura</i> (<i>Citrus medica</i>) <i>Tinduka</i> (<i>Diospyros peregrina</i>) <i>Amlaki</i> (<i>Embelica officinalis</i>), <i>Jambu</i> (<i>Syzgium cumini</i>)
Vegetables	<i>Patola</i> (<i>Trichosanthes dioica</i>), <i>Shigru</i> (<i>Moringa oleifera</i>), <i>Methika</i> (<i>Trigonella Foenum</i>), <i>Karavellaka</i> (<i>Momordica Charantia</i>), <i>Karkatee</i> (<i>Cucumis utilissimus</i>), <i>Gojihawa</i> (<i>Onosma bracteatum</i>)

Table no.8. Showing *Pathya vihara* in *prameha*

<i>Varga</i>	<i>Ahara</i>
<i>Shareerika vyayama</i> [Aerobic or cardio]	<i>Chankraman</i> [Brisk walking]
	<i>Riding on horse or elephant</i>
	<i>व्यायाम(अंगानाम् विविध प्रकार आयाम)</i> <i>Different body stretching exercise</i>
<i>High intensity training</i>	<i>Kreeda</i> [Sports activity]

Balavanatah prashikshana [strength training]	Niyudda [Wrestling]

Table no. 09. Showing Yoga in Prameha [helpful in flexibility, balance, and mind-body connection fitness] ⁷³.

Type of Yoga		Particular
Cleansing practices [Shuddi kriya]		Kapala bhati [frontal brain purification]
		Agnisara kriya [stimulating digestive fire]
		Vamana dhauti [Stomach cleansing]
		Shanka prakshalana [Intestinal cleansing]
Preparatory practices/warm up		Surya namaskara
Yoga postures [Asanas]	Standing postures	Trikonasana (Triangle pose)
		Tadasana (Palm tree pose)
		Tiryak tadasana (Bent palm tree pose)
		Veerasana (Warrior pose)
	Seated postures	Vakrasana (Spinal twist)
		Arda matsyendriyasana (seated spinal twist)
		Mandukasana (frog pose)
		Ushtrasana (camel pose)
		Paschimottasana (Seated forward bend)
		Yoga mudra (forward bend)
	Prone poses	Bhujangasana (Cobra pose)
		Dhanurasana (bow pose)
		Naukasana (boat pose)

		Makarasana (Crocodile pose)
	Supine poses	Pawana muktasana (wind relieving pose)
		Supta vajrasana [Supine thunderbolt pose]
		Setu bandasana [bridge pose]
		Matsyasana [fish pose]
		Shavasana [corpse pose]
	Inversion	Sarvangasana [shoulder stand]
		Halasana [plough pose]
Pranayama [Breathing practices]		Anuloma viloma [alternative nostril breathing]
		Chandra bhedana [left nostril breathing]
		Surya bhedana [Right nostril breathing]
		Bhastrika [Bellon’s breathing]
		Sheetali/sheetkari [cooling breath]
Bandha [Lock]		Uddiyana bandha [Abdominal lock]
Mudras		Linga mudra
		Surya mudra
		Prana mudra
		Apana mudra
		Gyana mudra
Relaxation yoga		Meditation
		Aum chanting
		Yoga nidra

Table no 10. Showing *Apathya ahara* and *vihara* in *prameha*⁷⁴

<i>Apathya ahara</i>	<i>Apathya vihara</i>
<i>Shali</i> (rice), <i>Navina dhanya</i> (freshly harvested grains).	<i>Aasyasukha</i> (sitting in a comfortable position on chair with back support or movable chair)
<i>Masha</i> (<i>Vigna mungo</i>), <i>Nishpava</i> (<i>Dolichos lablab</i>)	<i>Swapnasukha</i> (long duration of sleeping)
<i>Gramya mamsa</i> (meat of domestic animals) <i>Oudaka mamsa</i> (aquatic animals) <i>Anupa mamsa</i> (marshy animals)	<i>Madyapana</i> (consumption of alcohol)
<i>Payasa</i> , (kheer rice pudding), <i>Mandaka</i> Dadhi (curd)	<i>Avyayama</i> (avoidance of exercise)
<i>Ikshurasa</i> (sugarcane juice), <i>Ksheera</i> (milk) with sugar, newly made wine, curd, different kinds of fermented beverages	<i>Ratrijagarana</i> (awakening in night)
Oil cake of <i>tila</i> , pastry, <i>payasa</i> (kheer rice pudding), <i>Krashra</i> (gruel)	Excessive <i>Shodhana</i> therapy
<i>Aluka</i> (potato)	<i>Divashswapana</i> (sleeping in daytime)

f. Ayurvedic dietary principles

- i. The fundamental ideas included personalization to match the components of existence, body kinds, occupations, and the local and seasonal availability of ingredients, all while minimizing waste.
 1. Food would be season specific.
 2. Ideally, meals should have all six tastes: sweet, sour, salty, pungent, or spicy, bitter, and astringent. A traditional meal was mostly plant-based, with grains (cereals, millets), pulses, a variety of spices (such as pepper, cumin, coriander, and ginger), local seasonal vegetables and fruits, and a milk-based product (yogurt, buttermilk, and cottage cheese) to meet daily energy, macronutrient, micronutrient, fibre, and antioxidant requirements.
 3. Non vegetarians consume eggs, poultry, fish, and meat in moderation. They cook with cold-pressed oils and milk-based clarified butter to provide energy and increase nutritional absorption. Meals are balanced in terms of nutrition, flavour, and texture. Food is processed for storage and preservation without refrigeration. Natural, home-cooked meals are eaten daily, while elaborate, high-fat cuisine is reserved for special occasions.
 4. The plethora of functional foods provided a wide spectrum of essential nutrients. Processing procedures such as sprouting, malting, and fermentation increased nutrient content, aided digestion and assimilation, and provided additional health advantages. Many of these old traditions continue to be practiced in India today.
 5. The 'Plate Method' has been practiced for generations under the name 'Thali', which means plate in several Indian languages. The premise of Thali is to give nutritionally balanced meals in a variety of textures and

Flavors while controlling portion sizes by using small bowls for each cuisine. Foods from all food groups, including whole grains, vegetables, pulses or non-vegetarian options, and dairy products, are included.

Table no. 11. Showing different cooking methods in India.

Cooking Methods	Nutrition Highlights
Combination of grain and pulse (<i>Khichdi/ pongal/ idli/dosa/ dhokla/ dal baati/ zunka</i> or <i>pitla bhakar/ dal dhokli/ handvo/ thalipeet/ puttu kadala/ dal paratha</i>).	Cereals and pulses complement one another in a 3:1 ratio, delivering complete protein with all essential amino acids while lowering the Glycemic index (GI) of meals.
Fermentation (<i>idli/ dosa/ dhokla/ enduri pitha/ curd/ selroti/ambeli/khaman/sez/adai/vada</i>)	Fermentation of microorganisms produces enzymes that aid digestion, boosts probiotic activity, and promotes gut health and immunity. It also reduces antinutritional components, reduces flatulence, and boosts vitamin B and C levels in <i>idli</i> and <i>dosa</i> batter. Fermenting milk into yogurt converts lactose into lactic acid, benefiting lactose intolerant individuals.
Cooking and cooling starchy foods	Retrogradation (re-crystallization of starch polymer chains following gelatinization) increases the resistant starch type 3 (RS 3) concentration, lowering the GI. RS3 is

	generated after starchy foods have been cooked, cooled, and kept for several hours. Cooked and cooled potatoes, grains, and legumes have been demonstrated to contain high quantities of RS3.
Soaking (pulses and cereals)	Soaking before cooking decreases cooking time, improves digestibility, and removes antinutritional substances such as phytates, tannins, and enzyme inhibitors.
Steaming (vegetables)	One of the greatest cooking methods for conserving nutrients, including water-soluble vitamins that are susceptible to heat and water, such Vitamin C and B complex, as well as phytochemicals.
Sand Roasting (Popped, puffed, and flaked rice and maize; roasted cereals and millets; roasted legumes such as groundnut, chickpea, pea, cowpea)	It is the simplest and least expensive method of applying dry heat. High-temperature, short-term sand treatment improves puffing, crispiness, volume, colour, aroma, flavour, and texture while increasing shelf life. Sand roasting improves carbohydrate and protein digestibility, β -glucan extractability, prebiotic dietary fibre, minerals, and antioxidants, while lowering anti-nutrient levels in grains

	and legumes. The eradication of seed microflora extends shelf life and increases consumer acceptance. These roasted rice, wheat, maize, millets, and legume recipes are nutritious alternatives to today's harmful snacks.

- **Essential components of Indian traditional nutrition**

- Carbohydrates from rice, wheat, maize, various millets, amaranth, barley, starchy vegetables, fruits. Indian meal is a combination of grains, pulses, vegetables, and dairy.
- Dietary fiber
 - Soluble fibre is needed for proper nutrition. Vegetables, fruits, whole grain cereals, millets, and whole pulses all contribute to Indian cuisine's, high fibre content.
 - Vegetables can be eaten in a variety of ways, including salads, accompaniments, spiced pastes (chutneys), and mixed with curd.
 - Some vegetables are pickled (turnips, carrots, or black carrots) or preserved (mint, fenugreek, or moringa leaves) for later use. A wide range of green, leafy plants, including spinach, fenugreek, amaranth, and mustard, are employed. These give iron, calcium, vitamins, antioxidants, and fibre without increasing calorie or carbohydrate intake.
- Rice usage in India

- Processed in a way to reduce glycaemic index.
 - Use hand-pounded brown, red, or black rice.
 - Use parboiled rice rather than polished white rice.
 - Using old (stored and aged) rice.
 - Use cooked rice that has cooled overnight.
 - Combining rice with protein sources such as legumes, yoghurt, cottage cheese, eggs, fish, chicken, and meat.
 - Adding reasonable amounts of ghee, nuts, and seeds.
 - Adding rice and vegetables to a mixed dinner.
 - Adding lemon juice or tamarind to rice meals.
- Wheat consumption in India
 - For T2DM, it is recommended to consume whole wheat flour above refined flour-based products.
 - Emmer or 'Khapli' wheat (*Triticum dicoccum*), one of the world's oldest cereals, was among the earliest cereals to be produced on India's rich plains and is now being reintroduced. Compared to polished wheat, it is more disease-resistant, contains more dietary fibre (almost 9-20%), amylose, protein, and ash, has less fat and carbohydrate, and hence has a lower GI.
 - Traditional way of reducing glycemic index of wheat
 - Made using whole wheat flour and Khapli (Emmer) wheat, as well as broken wheat and bigger grit semolina.

- Combine bran and pulse flours (e.g., gram flour, soya flour, millet flour) with whole wheat flour.
 - Add grated or pureed vegetables, green leafy vegetables, herbs, and spices.
 - Knead whole wheat flour with yogurt, whey, milk, leftover pulse curry, or vegetable curry.
 - Fill whole wheat chapati/parathas with protein-rich ingredients including eggs, minced meat, cottage cheese, lentils, and vegetables.
 - Use modest amounts of fat.
- Barley consumption
 - It is consumed as flatbread and porridge. Barley reduces the GI of the chapati when mixed with whole wheat flour.
 - Millet usage
 - Millets commonly used in India are finger millet, pearl millet, sorghum, barnyard millet, foxtail millet, kodo millet, proso millet, and little millet.
 - Millets can replace rice and wheat in a variety of cuisines, including flatbreads, crepes, dumplings, idlis, pancakes, soups, and salads. Most millet has a lower GI than wheat and rice, making them advantageous for diabetics. The exception is finger millet, which has a high GI of 84. Millets are beneficial to persons who suffer from celiac disease because they are gluten-free.
 - Proteins

- Traditional Indian meals include cereals, pulses, nuts, and seeds, as well as low-fat dairy products, to provide high-quality protein for vegetarians.
- Nuts and seeds.
 - Nuts such as cashews, almonds, walnuts, sesame, pistachio, and pine nuts, as well as less expensive seeds like melon, watermelon, pumpkin, cucumber, flaxseed, and peanuts, are often used in gravies, salads, rice, beverages, sour chutneys, and sweets. They have few carbohydrates and are high in monounsaturated fatty acid (MUFA), protein, fibre, and antioxidants. Walnuts and flax seeds are good providers of omega-3 fatty acids. Bengal gram, peanuts, or sesame seeds baked into ladoos or bars (chikki) with jaggery/dates make wonderful healthful sweets, especially before, during, and after intense play or before bedtime, to prevent hypoglycaemia.
- Prebiotics and Probiotics
 - Prebiotics are non-digestible carbohydrates that gut bacteria consume; their relevance in sustaining gut health is now recognized. As previously noted, traditional Indian diets contained a variety of insoluble resistant starches, which provide beneficial prebiotic activity. Probiotics are live organisms that, when supplied in suitable proportions, provide health benefits to the host such as gastrointestinal functionality, metabolic equilibrium, cholesterol reduction, and obesity prevention, among others. Fermented foods are common in

Indian cuisine and include an abundance of probiotics. Fermentation improves nutrient bioavailability, food digestion, look, flavor, and scent. The examples include live-culture yogurt (lactobacillus, acidophilus, thermophiles, and bifidus), buttermilk, fermented vegetables, and sour pickles.

- Meal timings:
 - According to ancient Indian literature, eating is an important preventive and curative tool. They recommend eating in right portions, at proper times, sitting on the floor, and eating as a family to 'intensify the digestive fire'. The International society for paediatric and adolescent diabetes (ISPAD) 2018 guidelines emphasize the importance of meal-time routines that limit snacking to increase nutritional quality and optimize glycaemic results. Regular mealtimes and rituals in which the child and family sit down and eat together assist to create better eating habits and food intake monitoring.
 - This is linked to better glycaemic results. The Samhitas or Vedas advocate finishing dinner before sundown, avoiding sleeping on a full stomach, waking up early ("with or before the sun"), and taking a short afternoon siesta. This was appropriate for the tropics and a useful method of intermittent fasting. In regions where schools start early and conclude by early afternoon, this cycle can be mimicked by early awakening, post-lunch nap, and early night supper, as late dinner or late bedtime have been shown to correlate to obesity⁷⁵.

3. Review on Type 2 Diabetes mellitus

Diabetes Mellitus is a metabolic disorder with a diverse nature, primarily marked by the shared characteristics of impaired fat and protein metabolism.⁷⁶ T2DM constitutes approximately 90% of all diabetes cases. In T2DM, there is a reduced response to insulin, known as insulin resistance. In this condition, insulin loses its effectiveness, and initially, the body compensates by producing more insulin to maintain stable blood glucose levels.⁷⁷ However, as time passes, insulin production declines, leading to the development of T2DM. While T2DM is commonly observed in individuals aged 45 and above, it is becoming increasingly prevalent in children, teenagers, and young adults due to the growing prevalence of obesity, lack of physical activity, and consumption of high-calorie diets.⁷⁸

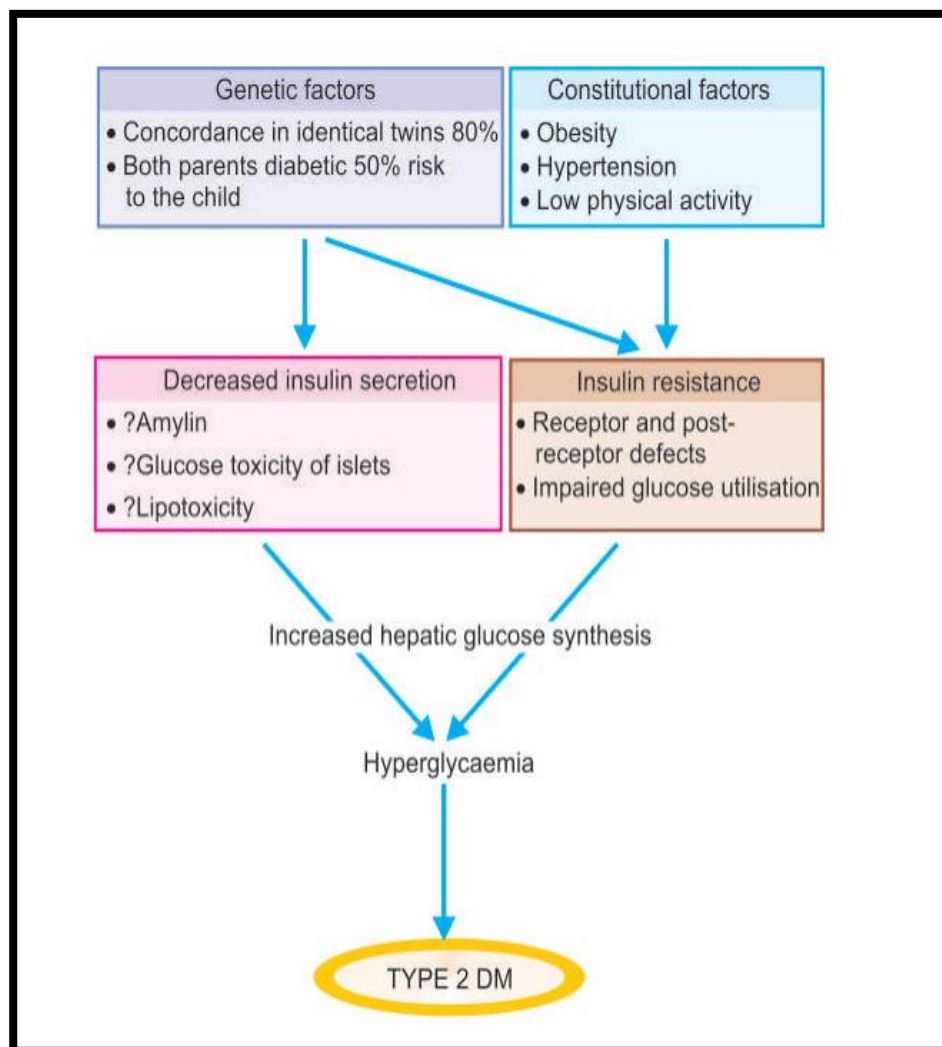
Major risk factors for T2DM:⁷⁹

1. Family history of T2DM
2. Obesity
3. Physical inactivity
4. Ethnicity and race (Asians, Blacks, Pacific islanders)
5. Previous identity of impaired glucose tolerance and impaired fasting glucose
6. History of gestational T2DM or delivery of baby heavier than 4 kg
7. Hypertension
8. Dyslipidemia (High density lipoprotein (HDL) level < 35 mg/dl or triglycerides > 250 mg/dl)
9. Polycystic ovary disease and acanthosis nigricans

10. History of vascular disease

Etiopathogenesis:⁸⁰

The fundamental metabolic issue in T2DM mellitus is characterized by either a delayed release of insulin compared to the amount of glucose present, which is known as impaired insulin secretion, or the body's peripheral tissues being unable to effectively react to insulin, which is referred to as insulin resistance.

Fig. No.3: Pathogenesis of T2DM

1. Genetic factors

When it comes to T2DM mellitus, genetic factors play a more significant role compared to type 1A diabetes mellitus. Although specific and consistent genes have not been pinpointed, the development of T2DM is primarily influenced by multifactorial inheritance, which is the most crucial factor.

- 1) If one identical twin has diabetes, the likelihood of the other twin developing the disease is approximately 80%.
- 2) If an individual has a parent with T2DM mellitus, their risk of developing diabetes increases. However, if both parents have T2DM, the risk of their offspring acquiring the condition rises to 40%.

2. Constitutional factors

Specific environmental factors, including obesity, hypertension, and level of physical activity, have a contributory role and influence the expression of the disease phenotype.

3. Insulin resistance

Insulin resistance, especially in skeletal muscle and liver tissues, is a notable metabolic characteristic of T2DM mellitus. Of significance, obesity is closely linked to insulin resistance and, consequently, T2DM. The mechanism behind hyperglycemia in these cases can be explained as follows.

- 1) Resistance to action of insulin impairs glucose utilization causing hyperglycemia.
- 2) There is increased hepatic synthesis of glucose.

- 3) In obesity, hyperglycemia is associated with elevated levels of free fatty acids and cytokines such as TNF- α and adiponectin, which impact the responsiveness of peripheral tissues to insulin.

4. Impaired insulin secretion

In T2DM insulin resistance and insulin secretion are interlinked

- 1) During the initial stages of the disease, when insulin resistance occurs, there is a compensatory response of increased insulin secretion (known as hyperinsulinemia) to sustain normal blood glucose levels.
- 2) Over time, there is a decline in the ability of beta cells to secrete sufficient insulin, leading to the failure of insulin production. However, there is still some insulin secretion present in individuals with T2DM mellitus, albeit at mild to moderate deficiency levels. It is important to note that this deficiency is less severe compared to type 1 diabetes mellitus, but it does not result in a complete absence of insulin.

5. Increased hepatic glucose synthesis.

Insulin normally plays a crucial role in facilitating the storage of glucose as glycogen in the liver and suppressing the production of new glucose through gluconeogenesis. However, in T2DM mellitus, insulin resistance extends to the liver as well, meaning that even with elevated insulin levels during the early stages of the disease, gluconeogenesis in the liver is not adequately suppressed. Consequently, there is an increased synthesis of glucose by the liver, which contributes to hyperglycemia in individuals with T2DM.

Clinical Features:⁸¹

- 1) The symptoms of T2DM mellitus develop gradually and subtly over time.
- 2) In most cases, patients with T2DM mellitus do not exhibit symptoms at the time of diagnosis, which is typically made based on the presence of glucosuria, or hyperglycemia detected during a physical examination. However, some individuals may present with symptoms such as increased urination (polyuria) and excessive thirst (polydipsia).
- 3) Frequently, individuals with T2DM mellitus are obese and may experience unexplained weakness and unintended weight loss.
- 4) Metabolic complications like ketoacidosis are uncommon.

Diagnosis:⁸² (American diabetes Association 2007)

- HbA1c- > 6.5
- Fasting Blood Sugar- > 126 mg/dl
- Postprandial Blood Sugar- > 140 mg/dl
- Random Blood Sugar- > 200 mg/dl
- Urine Sugar- glycosuria present

Treatment: The main aim of management is to improve symptom of hyperglycemia and to minimize the risk of long term microvascular and macrovascular complications.⁸³

1. Treatment methods include⁸⁴
 - a. Dietary and lifestyle modifications
 - b. Oral- anti diabetic drugs

c. Injectable therapies

a) Dietary recommendation

- **Benefits of nutrition therapy**

Nutrition counseling that works toward improving or maintaining glycemic targets, achieving weight management goals, and improving cardiovascular risk factors (e.g., blood pressure, lipids, etc.) within individualized treatment goals is recommended for all adults with diabetes and prediabetes.

- **Goals of nutrition therapy**

- Achieve and maintain body weight goals.
- Delay or prevent complications of diabetes.

- **Nutritional requirements**

- Macronutrient requirements
 - Approximately 45% of calories come from carbohydrates, 36-40% from fat, and 16-18% from protein. Chosen carbohydrates will be with a low glycaemic index and load.
 - Increase fibre intake through food (e.g., vegetables, legumes, fruits, whole grains) or nutritional supplements. A minimum of 14 g of fibre per 1,000 kcal and around 50 g of fibre per day lowers glycaemic consequences.
 - Limit saturated fat to less than 7% of total calories. Consumption of trans fat should be minimized. Very-long-chain n-3 polyunsaturated fatty acid supplements were recommended.
 - Omega-3 fatty acids should be consumed in the form of fish or supplements. Eat 2-3 servings of fish every week. Protein

accounts for 10-35% of total energy consumption from high-quality sources such as meat, poultry, fish, eggs, milk, cheese, and soybeans⁸⁵.

- Eating patterns
 - Mediterranean-Style Eating Pattern
 - Focus on antioxidant-rich foods like vegetables, fruits, whole grains, legumes, seeds, nuts, and spices. The primary source of fat is olive oil, which contains MUFA, while fish, which contains polyunsaturated omega 3 fatty acids, is consumed in moderation, and dairy products are used on a low-to-moderate basis. On the other hand, red and processed meat is consumed very infrequently, usually only during special occasions⁸⁶.
 - Vegetarian or vegan eating patterns
 - A conventional vegan diet excludes any animal-derived items. The diet emphasizes on whole grains, legumes, fruits, and vegetables.
 - United states USDA Dietary Guidelines for Americans
 - Emphasizes a diverse range of vegetables, fruits, grains (at least half of which are whole), lower-fat dairy, protein sources, and oils. This diet reduces saturated and trans fats, added sweets, and sodium.
 - Low-fat diet

- Emphasizes vegetables, fruits, carbohydrates (e.g., breads/crackers, pasta, whole grains, starchy vegetables), lean protein sources (including beans), and low-fat dairy.
- Very low-fat diet
 - Includes fibre-rich vegetables, legumes, fruits, whole grains, non-fat dairy, salmon, and egg whites. Contains 70-77% carbs (with 30-60 g fibre), 10% fat, and 13-20% protein.
- Low-carbohydrate diet
 - Low-carbohydrate vegetables (such as salad greens, broccoli, cauliflower, cucumber, cabbage, and others); fat from animal products, oils, butter, and avocado; and protein from meat, chicken, fish, shellfish, eggs, cheese, nuts, and seeds. Some plants contain fruit (such as berries) and a wider variety of non-starchy veggies. Avoid starchy and sugary foods including pasta, rice, potatoes, bread, and desserts. There is no standard definition of "low" carbohydrate. In this review, a low-carbohydrate eating pattern is defined as limiting carbohydrates to 26–45% of total calories.
- Very low-carbohydrate diet [VLC]
 - It is like the low-carbohydrate diet, but it further restricts carbohydrate-containing items, and meals often contain more than half of their calories from fat. To induce nutritional ketosis, it is common to aim for 20-50 g of non-

fibre carbs per day. In this review, a VLC eating pattern is described as limiting carbohydrate to 26% of total calories.

- Dietary Approaches to Stop Hypertension (DASH)
 - Emphasizes vegetables, fruits, low-fat dairy products, whole grains, chicken, fish, and nuts, while limiting saturated fat, red meat, sweets, and sugary beverages. The sodium level may also be lowered.
- Paleo diet
 - Emphasizes foods often consumed during early human evolution, including lean meat, fish, shellfish, vegetables, eggs, nuts, and berries. Avoid grains, dairy products, salt, refined fats, and sugar⁸⁷.
- **Type of exercise and Physical Activity in T2DM [as per ADA⁸⁸]**
 - In patients with diabetes, the ADA recommends 150 min/week (distributed over at least 3 days) of moderate aerobic physical activity with no gaps longer than 2 days.
 - Resistance exercise, flexibility, and balance training, and reduced sedentary behavior throughout the day.

Table no.12. Showing the Physical activity protocol for T2DM [as per ADA]

Exercise training recommendations: types of exercise, intensity, duration, frequency, and progression			
	Aerobic	Resistance	Flexibility and Balance
Type of exercise	Prolonged, rhythmic activities using large muscle groups (e.g., walking, cycling, and swimming) c	Resistance machines, free weights, resistance bands, and/or body weight as	Stretching: static, dynamic, and other stretching; Yoga Balance (for older adults):

	May be done continuously or as HIIT	resistance exercises	practice standing on one leg, exercises using balance equipment, lower-body and core resistance exercises, tai chi
Intensity	Moderate to vigorous (subjectively experienced as “moderate” to “very hard”)	Moderate (e.g., 15 repetitions of an exercise that can be repeated no more than 15 times) to vigorous (e.g., 6–8 repetitions of an exercise that can be repeated no more than 6–8 times)	Stretch to the point of tightness or slight discomfort c Balance exercises of light to moderate intensity
Duration	At least 150 min/week at moderate to vigorous intensity for most adults with diabetes. For adults able to run steadily at 6 miles per h (9.7 km/h) for 25 min, 75 min/week of vigorous activity may provide similar cardioprotective and metabolic benefits	At least 8–10 exercises with completion of 1–3 sets of 10–15 repetitions to near fatigue per set on every exercise early in training	Hold static or do dynamic stretch. Repetitions of each exercise. Balance training can be any duration
Frequency	3–7 days/week, with no more than 2 consecutive days without exercise	A minimum of 2 nonconsecutive days/week, but preferably 3	Flexibility, Balance
Progression	A greater emphasis should be placed on vigorous intensity aerobic exercise if fitness is a primary goal of exercise and not contraindicated by complications c Both high intensity interval training (HIIT) and continuous exercise training are appropriate activities for	Beginning training intensity should be moderate, involving 10–15 repetitions per set, with increases in weight or resistance undertaken with a lower number of repetitions (8–10) only after the target number of repetitions	Continue to work on flexibility and balance training, increasing duration and/or frequency to progress over time

	most individuals with diabetes	per set can consistently be exceeded c Increase in resistance can be followed by a greater number of sets and finally by increased training frequency	

b) **Oral- anti diabetic drugs:**⁸⁹

Table. No.13: Oral drugs in T2DM

Class	Compound(s)	Dosage
Biguanides	Metformin	850 mg Immediate Release (IR), 1000 mg (IR), 1000mg (Extended release (ER))
Sulfonylureas (2 nd generation)	Glimepiride Glipizide Glyburide	4 mg 10 mg (IR), 10 mg (XL/ER) 6 mg (micronized), 5 mg
Thiazolidinedione	Pioglitazone	45 mg
a-Glucosidase inhibitors	Acarbose Miglitol	100 mg 100 mg
Meglitinides	Nateglinide Repaglinide	120 mg 2 mg

DPP-4 inhibitors	Alogliptin	25 mg
	Saxagliptin	5 mg
	Linagliptin	5 mg
	Sitagliptin	100 mg
SGLT2 inhibitors	Ertugliflozin	15 mg
	Dapagliflozin	10 mg
	Canagliflozin	300 mg
	Empagliflozin	25 mg

Injectable therapies:⁹⁰

Insulin- Actrapid MC- 40 U/ml

Rapidica- 40 U/ml

Monotard MC- 40 U/ml

Human Actrapid- 40 U/ml, 100 U/ml

Human Mixtard- 40 U/ml, 100 U/ml

3.2. Drug review.

- Review on *Madhumehari ghanavati*
- *Madhumehari ghanavati*, a polyherbal formulation, is a product of our affiliated pharmacy and has demonstrated beneficial effects in our clinical settings. *Madhumehari ghanavati* is an *Anubandha Yoga* developed by our affiliated pharmacy. It is a proprietary formulation that developed based of Ayurvedic principles catering to clinical needs effectively for over 30 years.
- It contains total of 10 ingredients -*Madhunashini*, *Amalaki*, *Hereetaki*, *Vibheetaki*, *Jambhu*, *Vijayasara*, *Daruharidra*, *Tamala patra*, *Guduchi* and *Haridra*.

1. *Madhunashini*

- **Botanical Name-** *Gymnema sylvestrae* R. Br
- **Family-** *Asclepiadaceae*
- **Synonyms-** *Meshashringi*, *Madhunashini*, *Vishani*, *Meshavalli*, *Meshavishanama*, *Meshavishani*.
- **Useful Part-** Leaf
- **Pharmacodynamics-**
 - **Rasa-** *Kashaya, Tikta*
 - **Guna-** *Laghu, Ruksha*
 - **Virya-** *Ushna*
 - **Vipaka-** *Katu*
 - **Doshakarma-** *Kaphavata shamaka*
- **Rogaghnakarma-** *Yakrit shotha*, *Pleeha vridhhi*, *Agnimandya*, *Vibandha*, *Madhumeha*, *Ikshumeha*

- **Chemical Constituents-** Gymnemic acid, tartaric acid, gurmardin, calcium oxalate, glucose, stigmasterol, betaine, and choline.
- **Related Research Updates-** Supplementation of the diet with *Gymnema Sylvestre* reduced polyphagia, fatigue, blood glucose (fasting and post-prandial), and glycated hemoglobin and there was a favorable shift in lipid profiles and in other clinico-biochemical tests. These findings suggest a beneficial effect of *Gymnema sylvestre* in the management of diabetes mellitus.⁹¹

2. *Dharuharidra*

- **Botanical Name-** *Berberis Aristata* DC
- **Family-** Berberidaceae
- **Synonyms-** *Daruharidra, Darvi, Kateyaka, Pitadaru, Parjanya, Pachampacha, Peeta, Kaliyaka, Parjani, Haridru, Kantankateri*
- **Useful Part-** Rhizome
- **Pharmacodynamics-**
 - **Rasa-** Tikta, kashaya
 - **Guna-** Ruksa, Laghu
 - **Virya-** Ushna
 - **Vipaka-** Katu
 - **Doshakarma-** Tridosha shamaka.
- **Rogagnakarma-** *Shotha, Vedana, Vrana, Aruchi, Vibandha, Shukrameha, Prameha, Kandu, Shitapitta, Kushtha.*
- **Chemical Constituents-** Berberine and berbamine
- **Related Research Updates-** Supplementation of the diet with *Berberis aristata* reduced polyphagia, fatigue, blood glucose (fasting and post-prandial),

and glycated hemoglobin and there was a favorable shift in lipid profiles and in other clinico-biochemical tests. These findings suggest a beneficial effect of berberis aristata in the management of diabetes mellitus.⁹²

3. *Haridara*

- **Botanical Name-** *Curcuma longa* Linn
- **Family-** Zingiberaceae
- **Synonyms-** *Rajani, Nisha, Gouri, Krimighna, Yoshitapriya, Varavarnini, Hattavilasini, Haridra.*
- **Useful Part-** Rhizome
- **Pharmacodynamics-**
 - **Rasa-** *Katu, Tikta*
 - **Guna-** *Ruksa, Laghu*
 - **Virya-** *Ushna*
 - **Vipaka-** *Katu*
 - **Doshakarma-** *Kapha pitta shamaka*
- **Rogaghnakarma-** *Shotha, Netrabhishyanda, Aruchi, Agnimandya, Yakridvikara, Kamala, Prameha*
- **Chemical Constituents-** Curcuminoides
- **Related Research Updates-** In animal models, curcumin extract delays diabetes development, improves β -cell functions, prevents β -cell death, and decreases insulin resistance. The present review focuses on pre-clinical and clinical trials on curcumin supplementation in T2DM and discusses the peculiar mechanisms by which curcumin might ameliorate diabetes management.⁹³

4. *Guduchi*

- **Botanical Name-** *Tinospora cordifolia* (Willd) Miers.
- **Family-** Menispermaceae
- **Synonyms-** *Guduchi*, *Madhuparni*, *Amrita*, *Amritavallari*, *Chhinna*, *Chinnaruha*, *Kundalini*, *Vatsadini*, *Chakrangi*, *Tantrika*, *Kundalini*, *Somavalli*, *Dhira*, *Vayastha*, *Mandali*.
- **Useful Part-** Stem
- **Pharmacodynamics-**
 - **Rasa-** *Kashaya*, *Tikta*
 - **Guna-** *Guru*, *snigda*
 - **Virya-** *Ushna*
 - **Vipaka-** *Madhura*
 - **Doshakarma-** *Tridosha shamaka*
- **Rogaghnakarma-** *Kushta*, *Vatarakta*, *Netraroga*, *Trishna*, *Daha*, *Aruchi*, *Agnimandya*, *Shoola*, *Yakridvikara*, *Kamala*, *Pandu*, *Prameha*, *Madhumeha*, *Mootra krichhra*, *Kushta*, *Jwara*, *Vishama jwara*, *Jeerna jwara*.
- **Chemical Constituents-** alkaloids, diterpenoid lactones, glycosides, steroids, sesquiterpenoid, phenolics, aliphatic compounds and polysaccharides
- **Related Research Updates-** *Guduchi* has potential immunomodulatory and cytotoxic effects. It mediate its anti-diabetic potential through mitigating oxidative stress (OS), promoting insulin secretion and by inhibiting gluconeogenesis and glycogenolysis, thereby regulating blood glucose. Alkaloids, tannins, cardiac glycosides, flavonoids, saponins, and steroids as the major phytoconstituents of *Tinospora cordifolia* have been reported to play an anti-diabetic role.⁹⁴

5. *Tamala Patra*

- **Botanical Name-** *Cinnamomum tamala* (Buch-Ham)
- **Family-** Lauraceae
- **Synonyms-** *Tamala patra, Patra, Patranamaka, Patraka, Tamala, Gandha patraka.*
- **Useful Part-** Leaves
- **Pharmacodynamics-**
 - **Rasa-** *Madhura, Katu*
 - **Guna-** *laghu, picchila, tikshna*
 - **Virya-** *Ushna*
 - **Vipaka-** *Katu*
- **Doshakarma-** *Kapha vata shamaka*
- **Rogaghnakarma-** *Arsha, Hrillasa, Aruchi, Peenasa, Atisara, Udara shoola, Kasa, Shwasa, Medoroga, Kandu, Kushta, Garbhashaya shaithilya*
- **Chemical Constituents-** Monoterpenes and Sesquiterpenes.
- **Related Research Updates-** Leaf extract of *Cinnamomum tamala* significantly lowered the blood glucose level and maintained body weight and lipid-profile parameters towards near normal range in diabetic animals.⁹⁵

6. *Hareetaki*

- **Botanical Name-** *Terminalia chebula* Retz
- **Family-** Combretaceae
- **Synonyms-** *Haritaki, Pathya, Abhaya, Kaystha, Putana, Haimavati, Avyatha, Chetaki, Shiva, Vaystha, Rohini*
- **Useful Part-** Fruit
- **Pharmacodynamics-**

- **Rasa-** *Kashaya pradhana Pancha rasa lavana varjita,*
- **Guna-** *Laghu, Ruksha*
- **Virya-** *Ushna*
- **Vipaka-** *Madhura*
- **Doshakarma-** *Tridoshashamaka*
- **Rogaghnakarma-** *Nadi daurbalya, Agnimandya, Shoola, Anaha, Gulma, Vibandha, Udara roga, Arsha, Kamala, Krimiroga, Vatarakta, Hriddaaurbalya, Prameha, Shukrameha, Mootra krichra, Mootraghata, Ashmari, Kushta, Visarpa, Vishamajwara.*
- **Chemical Constituents-** Chebulin, corilagin
- **Related Research Updates-** The supplementation of *Triphala* (The three Myrobalans) revealed significant lowering in the Blood Glucose levels at 5 gm level quantity. *Triphala* contained the active ingredient Menthol and Sorbitol which is believed to have hypoglycemic effect. The significant Glucose lowering effect (Fasting and Post prandial) could have been due to the action of the key active ingredients.⁹⁶

7. *Bibheetaki*

- **Botanical Name-** *Terminalia bellerica Roxb*
- **Family-** *Combretaceae*
- **Synonyms-** *Bibhitaka, Aksha, Karshaphala, Kaliphala, Bhutavasa, kalidruma, karnaphala, Kaliyugalaya.*
- **Useful Part-** Fruit
- **Pharmacodynamics-**
 - **Rasa-** *Kashaya*
 - **Guna-** *Laghu, Ruksha*

- **Virya-** Ushna
- **Vipaka-** Madhura
- **Doshakarma-** Tridoshashamaka
- **Rogaghnakarma-** Agnimandya, Palitya, Hridroga, Vrana, Netrabhishyanda, Vatavyadhi, Anidra, Chhardi, Arsha, Krimiroga, Vibandha, Rakta nishthivana, Ashmari, Klaibya, Jwara, Samanya daurbalya, Netraroga
- **Chemical Constituents-** Chebulin, corilagin
- **Related Research Updates-** The supplementation of *Triphala* (The three Myrobalans) revealed significant lowering in the Blood Glucose levels at 5 gm level quantity. *Triphala* contained the active ingredient Menthol and Sorbitol which is believed to have hypoglycemic effect. The significant Glucose lowering effect (Fasting and Post prandial) could have been due to the action of the key active ingredients.⁹⁶

8. *Amlaki*

- **Botanical Name-** *Phyllanthus emblica* Linn
- **Family-** Euphorbiaceae
- **Synonyms-** *Amalaki, Vayasya, Vrishya, Dhatriphala, Vayastha, Amritaphala, Amalaka, Tishyaphala.*
- **Useful Part-** Fruit
- **Pharmacodynamics-**
 - **Rasa-** Pancharasa (alavana) Amla (Pradhana)
 - **Guna-** Laghu, Ruksha, Sita
 - **Virya-** Sita
 - **Vipaka-** Madhura
- **Doshakarma-** Tridoshashamaka, especially Pittashamaka.

- **Rogaghnakarma-** *Paittika vikara, Daha, Palitya, Trishna, Udavarta, Kasa, Shwasa, Yakshma, Arsha, Hridroga, Raktvikara, Shukrameha, Pradara, Mootrakrichra, Visarpa, Jeernajwara, Daurbalya, Daha, Shotha*
- **Chemical Constituents-** Chebulin, corilagin
- **Related Research Updates-** The supplementation of *Triphala* (The three Myrobalans) revealed significant lowering in the Blood Glucose levels at 5 gm level quantity. *Triphala* contained the active ingredient Menthol and Sorbitol which is believed to have hypoglycemic effect. The significant Glucose lowering effect (Fasting and Post prandial) could have been due to the action of the key active ingredients.⁹⁶

9. Jambu

- **Botanical Name-** *Syzygium cumini* (Linn)
- **Family-** Myrtaceae
- **Synonyms-** *Jambu, Mahaphala, Phalendra, Surabhipatra, Raja jambu, Mahajambu Nilaphala, Syamala.*
- **Useful Part-** Seed
- **Pharmacodynamics-**
 - **Rasa-** *Kashaya, madhura, amla*
 - **Guna-** *Laghu, Ruksha*
 - **Virya-** *Sita*
 - **Vipaka-** *Katu*
- **Doshakarma-** *Pitta shamaka*

- **Rogaghnakarma-** *Madhumeha, Prameha, Sthoylya, Kushtha, Udarda, Visarpa, Shwitra, Shotha, Palitya, Abhighataja vedana, Bhagna, Atisara, Pravahika, Krimi, Dantashoola, Raktapitta, Raktavikara.*
- **Chemical Constituents-** Gallic acid, Glycosides
- **Related Research Updates-** Jamun fruit and seeds have potent prophylactic role against hyperglycemia.⁹⁷

10. Asana

- **Botanical Name-** *Pterocarpus marsupium Roxb.*
- **Family-** Fabaceae
- **Synonyms-** *Asana, Beejaka, Peetashalaka, Pitasara, Bandhookapushpa, Priyaka, Saradru, Sarjaka*
- **Useful Part-** Heart wood.
- **Pharmacodynamics-**
 - **Rasa-** *Kashaya, Tikta*
 - **Guna-** *Laghu, Ruksha*
 - **Virya-** *Ushna*
 - **Vipaka-** *Katu*
- **Doshakarma-** *Kaphapitta shamaka*
- **Rogaghnakarma-** *Madhumeha, Prameha, Sthoylya, Kushtha, Udarda, Visarpa, Shwitra, Shotha, Palitya, Abhighataja vedana, Bhagna, Atisara, Pravahika, Krimi, Dantashoola, Raktapitta, Raktavikara.*
- **Chemical Constituents-** Pterostilbene
- **Related Research Updates-** Antidiabetic, Antibacterial, antifungal, anti-inflammatory, Antioxidant, anti-arthritis, immune modulator, hepato protective, anti-histaminic.

Table no.14: Madhumeha ghana vati, latin name, rasa, guna, veerya, vipaka and Prabhava

Name of the ingredients	Latin name	Rasa	Guna	Veerya	Vipaka	Prabhava
Meshashringi	Gymnema sylvestre R. Br	Kashaya, Tikta	Laghu, Ruksha	Ushna	Katu	Useful in Yakrit shotha, Pleeha vriddhi, Agnimandya, Madhumeha, Ikshumeha
Dharuhaaridra	Berberis aristata DC	Kashaya, Tikta	Laghu, Ruksha	Ushna	Katu	Shohta, Vedana, Vrana, Aruchi, Vibandha, Shukrameha, Prameha
Haridara	Curcuma longa Linn	Katu, tikta	Ruksha, laghu	Ushna	Katu	Shohta, Netrabhishyanda, Aruchi, Agnimandya, Yakridvikara, Kamala
Guduchi	Tinospora cordifolia (Willd) Miers.	Kashaya, tikta	Guru, Snigda	Ushna	Madhura	Kushta, Vatarakta, Netraroga, Agnimandya, Shoola, Kamala
Tamala patra	Cinnamomum tamala (Buch-Ham)	Madhura, Katu	Laghu, picchila Tikshna	Ushna	Katu	Arsha, Hrillasa, Aruchi, Peenasa, Udara shoola, Kasa
Hareetaki	Terminalia chebula Retz	Kashaya pradhana	Laghu, ruksha	Ushna	Madhura	Nadi daurbalya, Agnimandya, Shoola, Udara roga,

						Ashmari
Bibheetaki	Terminalia bellerica Roxb	Kashaya	Laghu, ruksha	Ushna	Madhura	Agnimandya, Palitya, Hridroga, Ashmari, Shwitra, Shotha
Amlaki	Phyllanthus emblica Linn	Pancharasa (Lavanarahita)	Laghu, ruksha	Shita	Madhura	Paittika vikara, Udavarta, Arsha, Kamala, Shukrameha, Mootrakrichra
Jambu	Syzygium cumini (Linn)	Kashaya, Madhura Amla	Laghu Ruksha	Sita	Katu	Madhumeha, Prameha, Kushtha, Udarda, Visarpa
Asana	Pterocarpus marsupium Roxb.	Kashaya Tikta	Laghu Ruksha	Ushna	Katu	Madhumeha, Prameha, Udarda, Visarpa

Table no.15. Showing mode of action of herbs of *Madhumehari ghanavati*.

SL. No.	Name of the herb (Part used)	Common name/ Sanskrit name	Part	Potential health effects [Type of study]
1.	Gymnema sylvestre R. Br. [leaves]	<i>Meshashringi/ Gurmar</i>	1	Hypoglycemic (Animal/human), Lipid lowering potential ⁹⁸
2.	Pterocarpus marsupium Roxb. [heart wood]	Indian kino tree/ <i>Asana</i>	2	Antihyperglycemic, Anti inflammatory ⁹⁹ (Animal)
3.	Syzygium cumini Linn [seed]	Jamun / <i>Jambu</i>	2	Useful in insulin resistance ¹⁰⁰ (Animal/in vitro)

4.	Curcuma longa Linn [Rhizome]	Turmeric/ <i>Haridra</i>	1	Antioxidant ¹⁰¹ [Human, animal]
5.	Berberis aristata DC [stem]	Indian barberry/ <i>Daruharidra</i>	1	Antidiabetic, Lipid lowering ¹⁰² [Human]
6.	Terminalia chebula Retz [fruit]	<i>Triphala</i>	1	Antioxidant ¹⁰³ , Immunomodulator ¹⁰⁴ [In vitro]
	Terminalia belirica Roxb [fruit]			
	Emblica officinalis Gaertn [fruit]			
7.	Tinospora cordifolia willd [leaves]	Giloy/ <i>Guduchi</i>	1	Antiinflammatory ¹⁰⁵ [Animal, in vitro]
8.	Cinnamomum tamala (Buch,Ham) [Leaves]	Bay leaf/ <i>Tamala patra</i>	1/4th	Significance in oral glucose Tolerance test [OGTT], Antihyperglycaemic ¹⁰⁶ [Animal]

4. JUSTIFICATION

Achieving and maintaining glycemic control is a key aim for the treatment of T2DM. The chronic metabolic imbalance is associated with long term macro and microvascular complications¹⁰⁷. As per international treatment guidelines, Metformin is the first-line therapy with diet and exercise. If glucose control remains inadequate, Combination of metformin with other class of antidiabetic agents like sulfonylureas, dipeptidyl peptidase 4 inhibitors, thiazolidinediones, GLP-1 receptor agonists, or sodium-glucose co-transporter-2 (SGLT2) inhibitors are recommended¹⁰⁸. Despite advanced anti diabetic agents' usage, several factors contribute to poor glycemic control including lack of integrated care, clinical inertia among health care providers and poor patient adherence to self-care recommendations¹⁰⁹. The anti-diabetic medications are found to have risk of hypoglycemia, diarrhea, flatulence, Vit B12 deprivation, UTIs, renal impairment etc¹¹⁰.

Integrative approach often brings conventional and complementary approaches together in a coordinated way. It emphasizes a holistic, patient focused approach to health care and wellness often including mental, emotional, functional, spiritual, social, and community aspects and treating the whole person rather than one. It aims for well-coordinated care between different providers and institutions.¹¹¹ The integrative approach is especially important in improving self-efficacy and empowering the patient to make healthy changes that could provide significant benefit. Adherence to all treatments improves when patients believe they are actively involved in determining their plan of care. Treatments that belong within

the integrated approach changes over time as treatments that were once considered alternative gain enough evidence to become accepted as mainstream. Researchers are currently exploring the potential benefits of integrative approach in a variety of medical conditions including pain management¹¹², different neurological conditions¹¹³, cancer symptoms and treatment side effects¹¹⁴, cardiology etc. Integrative approach can be beneficial in T2DM because most of which involve self-management, healing approaches and lifestyle changes. Ayurveda herbal drugs like Jambu, Madhunashini, Triphala, vijayasara, tamala patra, daruharidra, haridra, guduchi have properties of increasing insulin sensitivity¹¹⁵, antihyperglycaemic¹¹⁶, anti-hyper lipidaemic¹¹⁷, antioxidant properties^{118,119} etc. have beneficial effect in T2DM. Ayurveda dietetics had a positive outcome in T2DM management¹¹⁹. Yoga, being lifestyle intervention, has been reported to be a successful complementary treatment for T2DM¹²¹. Together, they represent a cost-effective alternative to long-term prescription of palliative care.

Although there are numerous clinical trials that have evaluated Ayurveda drugs and herbs in T2DM but only one study has evaluated efficacy through whole system approach¹²², where in this study fasting insulin and Homeostatic model for assessment for insulin resistance (HOMA IR) parameters were not assessed as they are the important parameters to assess T2DM. Also, this study has been limited to less sample size warranting further research. To the best of our knowledge no study has evaluated the Integrative approach through interdisciplinary approach in T2DM. Currently, no clinical study with Ayurveda medications has assessed the Fasting Insulin & HOMA IR parameters. Therefore, there is a need for the integrated Ayurveda treatment which includes conventional antidiabetic medication, Ayurvedic polyherbal medication, Ayurveda Diet and Yogic intervention. Hence, the current

research is planned to evaluate the effect of protocol-based Ayurveda intervention in the management of uncontrolled type-2 DM. This approach could possibly help in better glycemic control, increase treatment compliance and quality of life, and could turn out to be a better comprehensive management strategy.

5. MATERIALS AND METHODS

Methodology for the study is described under following headings:

- 1) Pharmaceutical study
- 2) Analytical study
- 3) Clinical study

1. Pharmaceutical study:

- **Identification & Authentication:** Raw drugs of *Madhumehari ghanavati* were identified and authenticated in the AYUSH certified ASU drug testing Central research facility of KAHER'S Shri B.M.K. Ayurveda Mahavidyalaya, Belagavi.
- **Collection:** Raw drugs of *Madhumehari ghanavati* were procured from KLE *Ayurveda* Pharmacy, Khasbag, Belagavi.

- The procedure of preparation of trial drug

Table no.16. Showing Ingredients and Proportion (Coarse powder 40-60 mesh number) of **Madhumehari ghanavati**

Si.No	Ingredients	Proportion	Proportion (in grams) for 100 ml of kwatha
1	<i>Madhunashini</i> leaves (<i>Gymnema sylvestre</i> R. Br.)	1 part	7
2	<i>Asana</i> Heart wood (<i>Pterocarpus marsupium</i> Roxb):	2 Part	13
3	<i>Jambu</i> Seeds (<i>Syzygium cumini</i> Linn):	2 Part	13
4	<i>Haridra</i> Rhizome (<i>Curcuma longa</i> Linn):	1 Part	7
5	<i>Daruharidra</i> Stem (<i>Berberis aristata</i> DC)	1 Part	7
6	<i>Bibhitaki</i> Fruit (<i>Terminalia belirica</i> Roxb) <i>Haritaki</i> Fruit (<i>Terminalia chebula</i> Retz) <i>Amalaki</i> Fruit (<i>Emblica officinalis</i> Gaertn)	 1 Part	77
7	<i>Guduchi</i> (<i>Tinospora cordifolia</i> willd)	1 Part	7
8	<i>Tamala Patra</i> (<i>Cinnamomum tamala</i> (Buch,Ham))	1/4 th Part	1.5
9	Water	6 parts	40

Fig.04. Drug preparation steps.

1. As per specified quantity all coarse powders were taken in *khalva yantra* and a homogenous mixture was prepared.

2. The drug mixture was taken in stainless steel container and soaked in eight parts of tap water for 12 hrs.

3. Overnight soaked drug mixture was kept for boiling on moderate fire till it reduces to one fourth quantity. Pleasant Odour of *Kashaya* was observed during boiling. Filtered and kept aside.

4. The *Kashaya* was taken in Stainless steel vessel and kept for boiling; Boiling was continued till it attained the semisolid consistency.

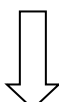
5. After attaining semisolid consistency, the vessel was removed from gas s. It was taken in a thick polythene sheet when it was warm and kept in shade for drying.

6. After drying completely, it was powdered, and a Size of 500 mg *Ghanavati* was prepared and stored in airtight container.

Image 1. Showing raw materials used in the *Madhumehari ghanavati*



Image 2. Showing *Madhumehari ghanavati* preparation.



Madhumeha Kashaya



Reheated Kashaya



Obtained Thick ghana



Dried form of Ghana



Powder form of Ghana



End product-Vati.

Image 3: Showing *Madhumehari ghanavati* finished and packed product.



2. Analytical study

Analysis of *Madhumehari ghanavati* was done in AYUSH certified ASU drug testing central Research facility of KAHER'S Shri B.M.K. Ayurveda Mahavidyalaya, Belagavi.

3. Clinical Study:

- The medical trial received approval from the KAHER ethical committee for human subjects.
 - **Ref ID: KAHER/EC/20-21/001/11**
- The institutional ethical committee approval was obtained to conduct clinical study.

- **BMK/21/PhD/SK**
- Study was registered in Clinical trial for Registry of India
 - Ref.no: **CTRI/2020/12/029762**

3.1 . Study type.

Study is a Randomized controlled parallel group open label clinical Trial.

3.1.2. Site of study.

Patients diagnosed with T2DM were selected from OPD & IPD of KLE Ayurveda Hospital & research Centre, Belagavi.

3.1.3. Sample size: 100 patients were enrolled in the study and randomly divided into two groups.

Table no.17: Showing patient allocation and group details

Group	Number of patients	Type	Description
STP	100	Control (standard control)	Patient in standard treatment protocol (STP) group. Undergone standard diabetic care
IATP	100	Trial (study group)	Patients in integrated Ayurveda treatment protocol (IATP)

3.1.5. Time points: Baseline, 30th, 60th and 90th day.

3.2. Study population:

3.2.1. Diagnostic criteria: Subjects with Uncontrolled T2DM (HbA1c of more than or equal to 7 -10.5%) ^{112,113}

3.2.2. Inclusion criteria:

1. Diagnosed subjects of T2DM with age between 18 to 70 years
2. Diabetic subjects with insufficient blood glycemic control for a period of 90 days before screening while on stable treatment with metformin ($\geq 1000\text{mg}$)
3. Glycosylated hemoglobin (HbA1c) between 7% -10.5%
4. Subject who submits a written informed consent

3.2.3. Exclusion criteria:

1. Subjects with uncontrolled hypertension (with BP more than or equal to 140/90 mmHg)
2. Subjects with established diagnosis of coronary artery disease (CAD) or any other clinically significant cardiovascular disease
3. Subjects with established cases of cerebro-vascular accidents such as stroke etc.
4. Subjects with diabetic neuropathy, diabetic retinopathy, diabetic nephropathy, diabetic wounds, or ulcers.
5. Pregnant and lactating women.

3.2.4. Withdrawal criteria:

- Any concomitant serious illness develops which require hospitalization.
- The patient himself /herself wants to withdraw from the study.
- In any arising clinical scenarios where guides/co-guides feel continuation of patient in the study is detrimental.
- Drug compliance less than 80 %.

3.2.5. Rescue medication:

- To alleviate any emergency, the use of rescue medication will be permitted as per the wisdom/discretion of the guide/co-guide. However, the same will be documented in the case report form (CRF).

3.2.6. Criteria for assessment:**Primary outcome measures:**

Changes in HbA1c level from baseline and in 90 days

Secondary outcome measures:

- Changes in fasting insulin level from baseline and in 90 days
- Changes in HOMA IR level from baseline and in 90 days
- Changes in fasting and post prandial blood sugar from baseline and at 30th, 60th and 90th days.
- Changes in lipid profile from baseline and at 90 days
- Changes in BMI and waist circumference at baseline and at 30th, 60th and 90th days
- Changes in Diabetes Quality of Life (DQoL): at baseline and at 30th, 60th and 90th days

3.3. Study Design:

- The study was a randomized, standard controlled, parallel group, open label, single centric trial.
- The study employed a block design for randomization, ensuring a balanced 1:1 allocation ratio between control and trial groups.
- The random sequence generation is through online software and the principal investigator managed online random sequence generation and opaque envelope sealing for allocation concealment which were blinded by the investigator.
- The administration, distribution, and randomization of study-related materials were handled by different research teams.

3.4: Study group

Control Group:

- Standard treatment protocol (STP) group
 - Will receive standard diabetic care which includes,
 - Standard treatment with metformin($\geq 1000\text{mg/day}$)
 - Add on treatment with other classes of anti-diabetic medications.
 - Nutritional and lifestyle management counseling

Trail group [Study group]:

- Integrated Ayurveda treatment protocol (IATP) group.
 - Will receive Integrated ayurveda care which includes,
 - Stable treatment with metformin ($\geq 1000\text{mg/day}$)

- Add on intervention of *Ayurvedic* polyherbal formulation- *Madumehari ghanavati* weighing 500 mg 2 tab thrice daily after food with lukewarm water for a duration of 90 days.
- Ayurveda Dietary intervention:
 - Diabetic food ingredients mentioned in Ayurveda literature will be included in diet chart.
 - Assessment of *Agni* (Digestive Fire), Body mass index will be done prior to the diet administration.
 - Diet requirement calculation will be done considering the type of activity of participants and BMI.
 - Individual diet chart given for classified participants such as Underweight (*Krishha*), Normal (*Madhyama*), overweight & Obese (*sthula*)
- Yoga intervention:
 - Yoga-based lifestyle changes with components of breathing practices, loosening practices, *surya namaskara*, *asanas*, *pranayama*, relaxation techniques and meditations.
- **Ayurveda diet:** The study aimed to implement dietary interventions based on the dietary principles of Indian traditional medicine [*Ayurveda diet*]. A literature review and detailed local dietary practices were conducted to prepare a diet plan. The recommended calorie intake was calculated to manage portion control, considering the patient's physical activity and weight. The plan was validated by a senior nutritionist with over 10 years of diabetes experience. Inputs were considered, and modifications were made. The diet consists of three main meal patterns. The main meal is consumed

between 10 a.m. and 2 p.m., and the evening meal as an easily digestible dinner. Meals typically contain 20 to 25% protein, 50 to 55% carbohydrates, and 20 to 25% healthy fat sources. Beans and lentils are preferred for breakfast, while millet-based grains are served for lunch and dinner with vegetables and fat sources. We followed the ‘plate method’[Traditional thali] which suggests dividing a plate into half vegetables, one-fourth with millets or barley, and the remaining one-fourth with protein and good fats. To prevent excess carbohydrates, two-thirds were vegetables and low-glycemic index fruit, while one-third came from grains and starchy vegetables. Barley and millet varieties are used instead of refined grains. The Ayurveda diet focuses on soluble fiber from whole grains, beans, lentils, seeds, herbal juices, vegetables, and fruits. Morning drinks like herbal infusions or green vegetable smoothies are used. Good fat sources like flax, sesame, safflower, fenugreek, and peanuts are used in traditional Indian chutney’s (spicy condiment) and most food with clarified butter toppings. This diet plan is well-balanced, healthy, palatable, and caters to diabetes requirements

- **Yoga protocol.**

Table no. 18: Therapeutic Yoga technique with appropriate duration and remarks

Name and duration	Posture	Practices
Breathing exercise (5 minutes)	Standing	Hand stretch and breathing [5 min]
Body loosening exercise (5 min)	Standing	5 min <i>Padahastasana</i> (hand to foot pose) <i>Ardha chakrasana</i> (half wheel position) The <i>Trikonasana vyayama</i> (Triangle pose)

		<i>Kati parivartana vyayama</i> (spinal twist)
	Sitting	5 minutes <i>Chakki chalana</i> (mill churning pose) <i>Bhunamanasana</i> (Earth pose)
	Supine	Wind relieving swing posture
	Prone	<i>Dhanurasana</i> swing (bow swing posture)
Relaxation for 5 min	-	Instant relaxation technique
<i>Suryanamaskara</i> (sun salutation) for 5 min	-	Specific sequence of 12 yoga poses (12 cycles)
Yoga exercise (10 min each)	Standing	<i>Arda kati chakrasana</i> (half-wheel position) <i>Parivratta trikonasana</i> (twisted triangle position)
	Sitting	Spinal twist pose <i>Arda matsendriyasana</i> (Posing as a half-lord of the fishes)
	Prone	<i>Bhujangasana</i> (Cobra posture) <i>Dhanurasana</i> (Bow position)
	Supine	<i>Pawana muktasana</i> (wind relieve posture) <i>Matsyasana</i> (Fish pose)
Relaxation for 10 min	Supine	Deep relaxation techniques
<i>Pranayama</i> (breathing practice-10 min)	Sitting	<i>Nadi shuddi</i> [Alternate nostril breathing technique] <i>Brahmari</i> [Humming bee breath] Aum Chanting
Meditation (20 min)	Sitting	Cyclic meditation

Table no.19: Assessment Parameters

Sl. No	Parameters	Base line	30th day	60th day	90th day
1	BMI, Waist circumference	✓	✓	✓	✓
2	Hb%	✓	-	-	✓
3	FBS	✓	✓	✓	✓
4	PPBS	✓	✓	✓	✓
5	Urine Sugar	✓	✓	✓	✓
6	Diabetes quality of life	✓	✓	✓	✓
7	HbA1C	✓	-	-	✓
8	Fasting Insulin	✓	-	-	✓
9	HOMA IR	✓	-	-	✓
10	Lipid profile	✓	-	-	✓
11	Serum creatinine	✓	-	-	✓

3.5. Study Duration:

Following the Ethics Committee approval the study was initiated, and recruitment and completion of trial was done over a period of maximum 30 months.

3.6. Informed Consent:

Informed written consent was obtained from each participant in the prescribed format prior to performance of study related procedures (i.e. physical examination, laboratory screening or any other investigational procedure). The participants were given full information about the study as well as a description of any foreseeable risks and discomforts. Participants were also informed of their right to opt out of the study at any time without giving any reasons.

3.7. Good Clinical Practice (GCP):

The study was conducted in accordance with the principles of Good Clinical Practice that has its principles as reported in the Declaration of Helsinki.

3.8. Sample size calculation:

Based on previously published quantitative clinical data, sample size calculation was performed using the given formula.

$$n = \frac{2S^2(Z\alpha + Z\beta)^2}{d^2}$$

In this formula, the following parameters of the previous study were used.

- The standard deviation (SD) of FBS in 1st group is 21.41 (S₁)
- The SD of FBS in 2nd group is 30.60 (S₂)
- The mean difference between the two group ($d = (\bar{x}_1 - \bar{x}_2)/2$) is 17.65.
- The combined SD is calculated as $S = \sqrt{(s_1^2 + s_2^2)/2}$,

With a Z α value 2.58 for a 1% α error and a Z β of 1.682 for 95 % power, the sample size was determined to be 80 participants per group to achieve 95 % power

and 1% α error. To account for a 20% attrition rate, a total sample size of 100 participants per group was considered adequate.

3.9. Statistical test:

Descriptive statistics (% , mean, standard deviation (SD), etc.) were used to summarize the data. Nonparametric tests, such as the chi-square test, were employed to assess the homogeneity of the data at baseline. Parametric tests, including the independent t-test and dependent t-test, were used to evaluate the effects of parameters between and within the groups. Statistical significance was considered at a level below 5% ($p < 0.05$).

6. OBSERVATIONS AND RESULTS

Results are mentioned in two groups.

6.1. Drug Analysis of *Madhumehari ghanavati*

1. Macroscopic, phytochemical standards of 9 drugs of *Madhumehari ghanavati*
2. Microscopic phytochemical analysis of *Madhumehari ghanavati*

Table no.20. Analytical report of *Madhumehari ghanavati* (macroscopic)

Macroscopic	
Test	Results
Form	Vati
Colour	Black
Odour	Characteristic
Physiochemical standards	
Test	Result
Loss on drying	1.796%
Water soluble extract	64.495%
Alcohol soluble extract	16.265%
Average weight	0.487 gram
Hardness(vertical)	4 kg/cm
Disintegration time	21 minutes

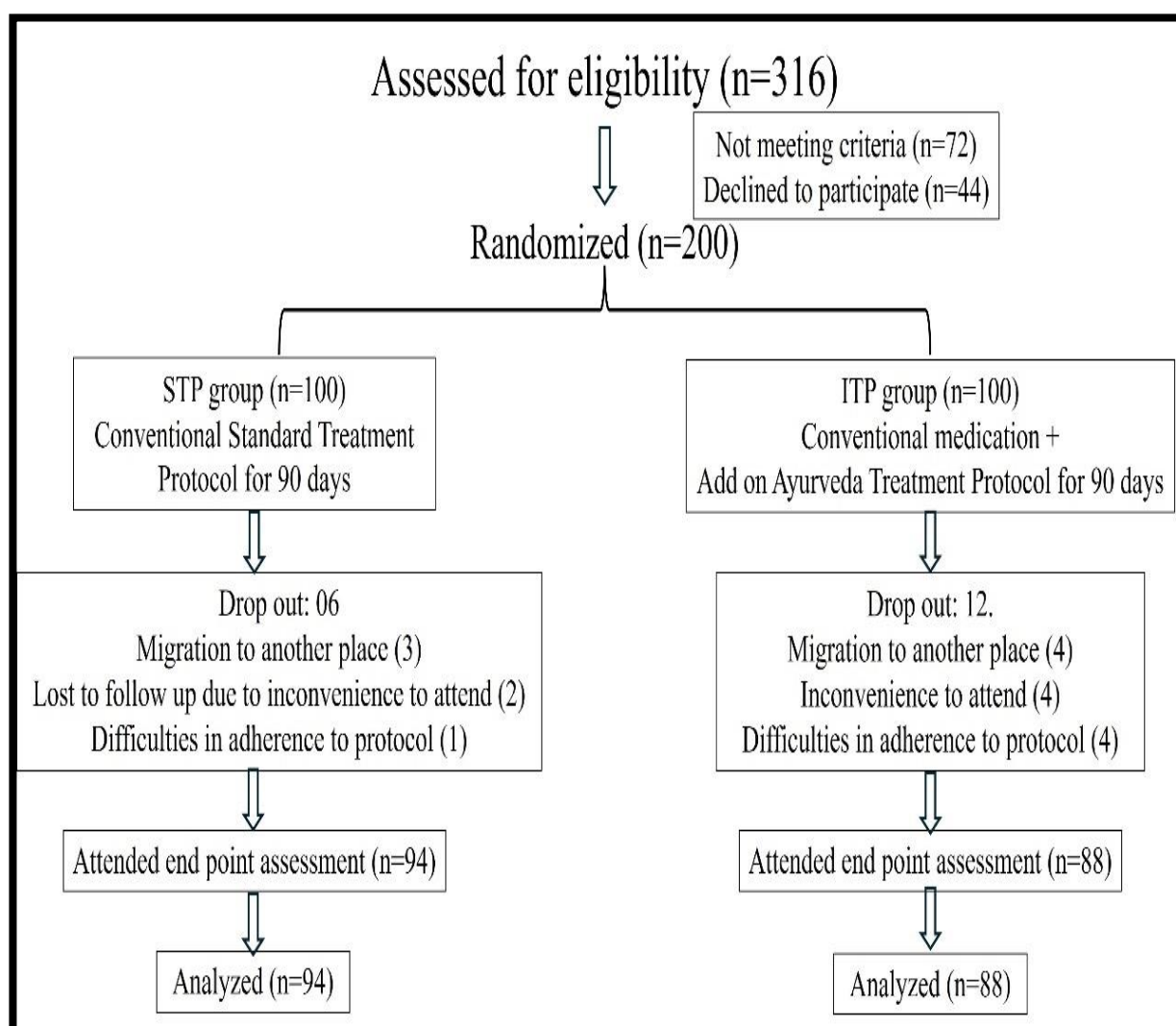
Table no. 21. Analytical report of *madhumehari ghanavati* (microscopic)

Test for specified Micro-organisms (Qualitative)	Limits (as per IP)	Results
E coli	Absent/100 ml	Absent
S Aureus	Absent/100 ml	Absent
P aeruginosa	Absent/100 ml	Absent
Microbial limit test (Quantitative)	Limits (As per IP)	Results
Total Bacterial count	30-300cfu/ml	07cfu/ml
Total Fungal count	10-100cfu/ml	03cfu/ml

6.2 Clinical Study

6.2.1 CONSORT CHART

Fig.05. Consort chart.



6.2.2. Observation

The study found that both STP and IATP groups had a similar distribution in terms of gender ($p=0.42$), education ($p=0.13$), socioeconomic position ($p=0.13$), occupation ($p=0.85$), diet ($p=0.19$), lifestyle factors ($p=0.29$), appetite ($p=0.740$), sleep ($p=0.8850$), caloric intake ($p=0.059$) and a family history of T2DM ($p=0.24$). There were significant differences in the age distribution ($p=0.02$), marital status ($p=0.04$), mean T2DM chronicity ($p=0.013$), medication duration ($p=0.02$), and metformin dosage ($p=0.0002$) in between STP and IATP group. Adherence to diet ($p=0.001$) and exercise/yoga practice was higher in IATP group ($p=0.0002$) compared to the STP group.

Table no.22: Age wise distribution of the patient

Characteristics	STP		IATP		Total		χ^2	p-value
	N	%	N	%	N	%		
Age groups								
<=40yrs	7	7.00	17	17.00	24	12.00	9.0860	0.0280*
41-50yrs	16	16.00	25	25.00	41	20.50		
51-60yrs	34	34.00	23	23.00	57	28.50		
>=61yrs	43	43.00	35	35.00	78	39.00		

The study found that most individuals in STP were above 61 years old (43%), followed by those aged 51-60 (34%), and in IATP, the majority were above 61 years old (35%), followed by those aged 41-50 (23%).

Table no.23: Gender wise distribution of the patient

Characteristics	STP		IATP		Total		χ^2	p-value
Gender	N	%	N	%	N	%	2.8200	0.4200
Male	53	53.00	54	54.00	107	53.50		
Female	47	47.00	46	46.00	93	46.50		

Males were more in number in both the groups i.e., in STP (53%) and in IATP (54%).

Table no.24: Religion wise distribution of the patient

Characteristics	STP		IATP		Total		χ^2	p-value
Religion	N	%	N	%	N	%	2.8200	0.4200
Hindu	92	92.00	86	86.00	178	89.00		
Muslim	3	3.00	3	3.00	6	3.00		
Christian	1	1.00	4	4.00	5	2.50		
Jain	4	4.00	7	7.00	11	5.50		

Maximum numbers of patients recruited in the study were from Hindu religion in both the groups i.e. in STP (92%) and in IATP (86%).

Table no.25: Education status wise distribution of the patient

Characteristics	STP		IATP		Total		χ^2	p-value
Education Status	N	%	N	%	N	%	8.4900	0.1310
Illiterate	6	6.00	1	1.00	7	3.50		
Primary School	31	31.00	31	31.00	62	31.00		
High School	21	21.00	22	22.00	43	21.50		
Diploma	0	0.00	3	3.00	3	1.50		
Graduate	37	37.00	33	33.00	70	35.00		
Postgraduate	5	5.00	10	10.00	15	7.50		

In both the groups, the maximum number of patients were graduates i.e., in STP (37%) and IATP (33%) followed by primary school education i.e 31% in both STP and IATP.

Graph no.01: Showing demographic variable (Age, sex, religion, education)

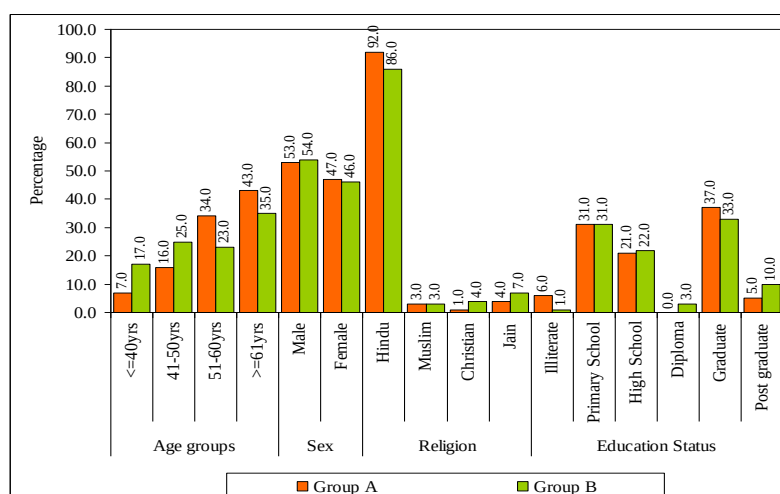


Table no.26: Occupation wise distribution of the patient

Characteristics	STP		IATP		Total		χ^2	p-value
Occupation	N	%	N	%	n	%	1.9550	0.8550
Agriculture	6	6.00	5	5.00	11	5.50		
Business	18	18.00	23	23.00	41	20.50		
Officer	29	29.00	22	22.00	51	25.50		
Home maker	32	32.00	35	35.00	67	33.50		
Teacher	5	5.00	4	4.00	9	4.50		
Labor	10	10.00	11	11.00	21	10.50		

Occupation wise distribution of subjects revealed that, majority (32% in STP and 35% in IATP) were homemakers followed by officers (29% in STP and 22% in IATP). Between the groups, there is comparable changes ($p=0.85$).

Table no.27: Socioeconomic status wise distribution of the patient

Characteristics	STP		IATP		Total		χ^2	p-value
SES	N	%	N	%	n	%	4.0140	0.1340
Poor	12	12.00	5	5.00	17	8.50		
Middle	75	75.00	76	76.00	151	75.50		
Upper	13	13.00	19	19.00	32	16.00		

Socioeconomic status-wise distribution of subjects revealed, maximum people belong to middle class group i.e. 75% in STP and 76% in IATP.

Table no.28: Marital status wise distribution of the patient

Characteristics	STP		IATP		Total		χ^2	p-value
Marital Status	N	%	N	%	n	%	8.1600	0.0430*
Married	94	94.00	83	83.00	177	88.50		
Unmarried	0	0.00	6	6.00	6	3.00		
Divorced	1	1.00	2	2.00	3	1.50		
Widowed	5	5.00	9	9.00	14	7.00		
Total	100	100.00	100	100.00	200	100.00		

In both the groups, the majority were married, i.e. 94% in STP and 83 % in group. Between the groups there is significant difference in age wise distribution of subjects.

Graph no.2: Showing occupation, socioeconomic status, and marital status.

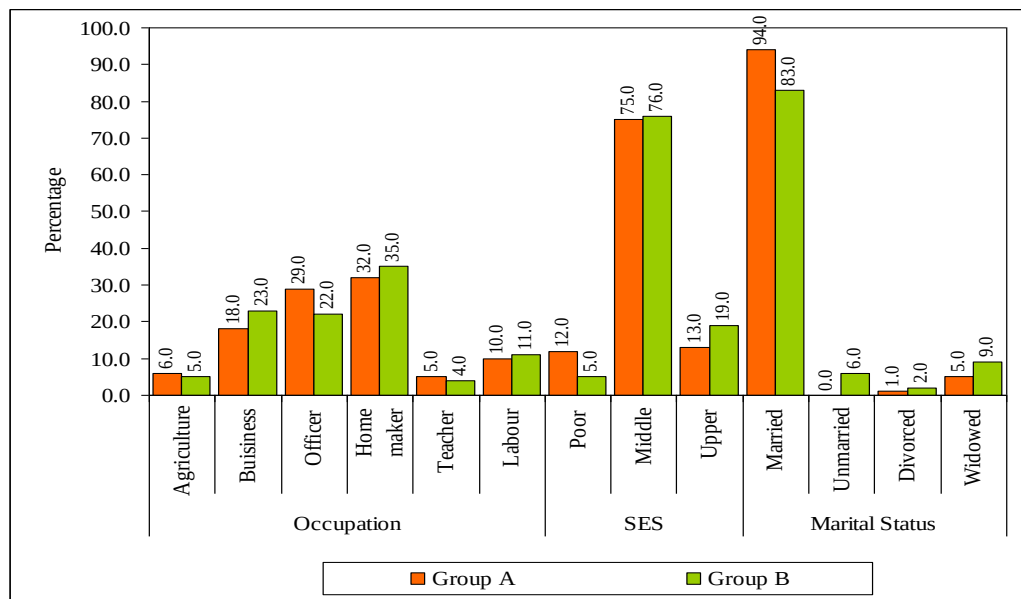


Table no.29: *Desha* wise distribution of the patient

Characteristics	STP		IATP		Total		χ^2	p-value
<i>Desha</i>	N	%	N	%	n	%	2.0200	0.3640
<i>Sadharana</i>	97	97.00	99	99.00	196	98.00		
<i>Anupa</i>	2	2.00	0	0.00	2	1.00		
<i>Jangala</i>	1	1.00	1	1.00	2	1.00		

Maximum number of subjects belongs to *sadharana desha* i.e 97% in STP and 99% in IATP.

Table no.30: T2DM chronicity and medication duration and dosage

Variable	STP		IATP		T value	P value
	Mean	Std.dev	Mean	Std.Dev		
Chronicity of T2DM in years	6.61	4.34	5.18	3.75	2.5015	0.0132*
Medication duration in years	6.41	4.26	5.06	3.91	2.3348	0.0206*
Dose(mg)	1490.00	426.28	1284.00	348.36	3.7419	0.0002*

In STP, there is mean chronicity of 6.6 years and in IATP there is mean chronicity of 5.18 years. Between the groups, there is a significant difference.

Graph no.3: T2DM Chronicity and medication duration.

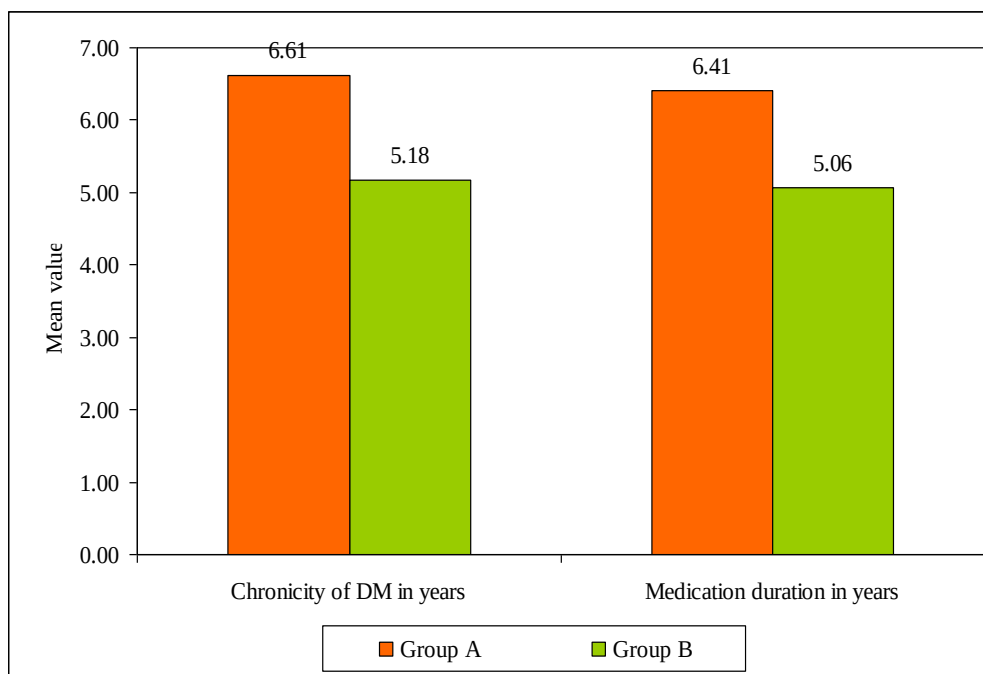
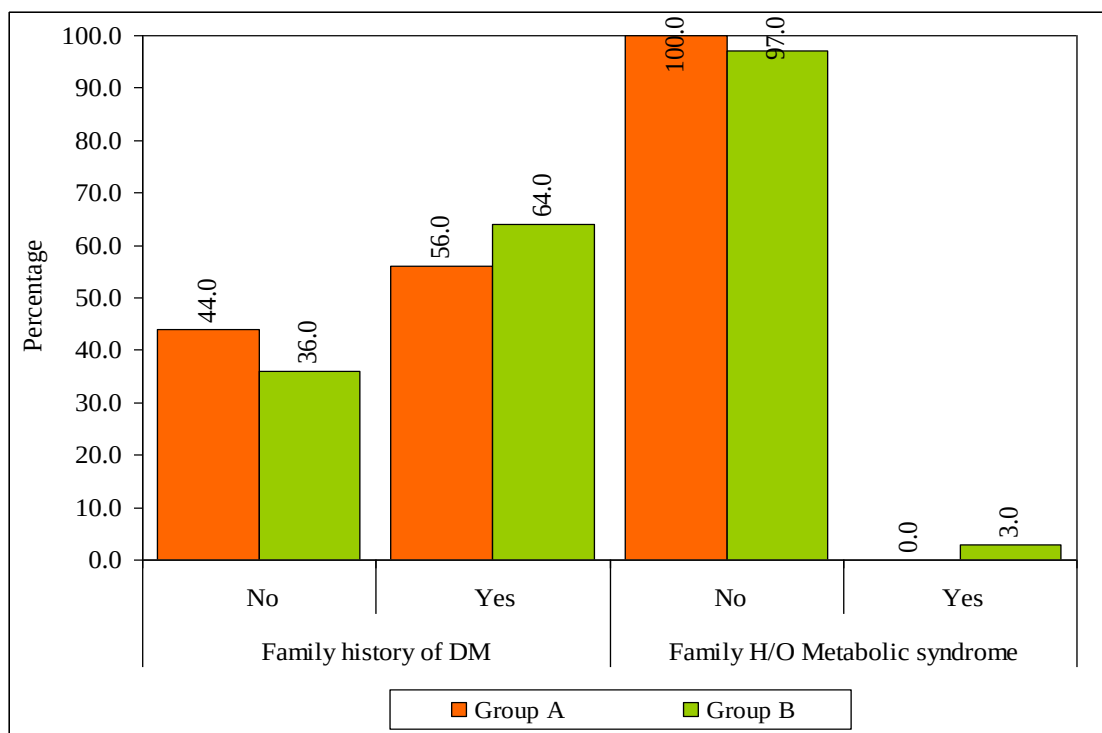


Table no.31: Family history wise distribution of the patient

Characteristics	STP		IATP		Total		χ^2	p-value
	N	%	N	%	n	%		
Family history of DM								
No	44	44.00	36	36.00	80	40.00	1.3330	0.2480
Yes	56	56.00	64	64.00	120	60.00		

Among the total sample, maximum population (60%) had family history of T2DM. Group wise distribution revealed, 56% had family history in STP and 44% in IATP. Between the groups, the observation was comparable ($p=0.24$).

Graph no.4: Showing family history of T2DM and metabolic syndrome.**Table no.32: Personal History wise distribution of the patient**

Characteristics	STP		IATP		Total		χ^2	p-value
	N	%	n	%	n	%		
Bowel								
Regular	72	72.00	71	71.00	143	71.50	1.1770	0.7580
Irregular	16	16.00	18	18.00	34	17.00		
Irregular, Constipated	9	9.00	10	10.00	19	9.50		
Regular, constipated	3	3.00	1	1.00	4	2.00		

Personal history wise distribution of subject revealed, majority had regular bowel habit (72% in STP and 71% in IATP).

Table no.33: Sleep wise distribution of the patient

Variables	STP		IATP		Total		χ^2	P value
Sleep	N	%	n	%	n	%		
Normal	61	61.00	60	60.00	121	60.50	0.0210	0.8850
Disturbed	39	39.00	40	40.00	79	39.50		

Sleep wise distribution of subject revealed, majority had normal sleep schedule i.e. 61 % STP and 60% in IATP.

Table no.34: Appetite wise distribution of the patient

Variables	STP		IATP		Total		χ^2	P value
Appetite	N	%	n	%	n	%		
Normal	81	81.00	77	77.00	158	79.00	0.6010	0.7400
Increased	14	14.00	18	18.00	32	16.00		
Decreased	5	5.00	5	5.00	10	5.00		

Appetite wise distribution of subject revealed majority had normal appetite i.e 81% in STP and 77% in IATP.

Table no.35: Showing diet wise distribution of patients.

Variables	STP		IATP		Total		χ^2	P value
Diet	N	%	n	%	n	%		
Mixed	66	66.00	57	57.00	123	61.50	1.7100	0.1910
Veg	34	34.00	43	43.00	77	38.50		

Diet intake wise distribution of subject revealed majority was with mixed diet pattern i.e 66% in STP and 57% in IATP.

Graph no.5: Showing personal history wise distribution of patient [Bowel, sleep, appetite, Diet]

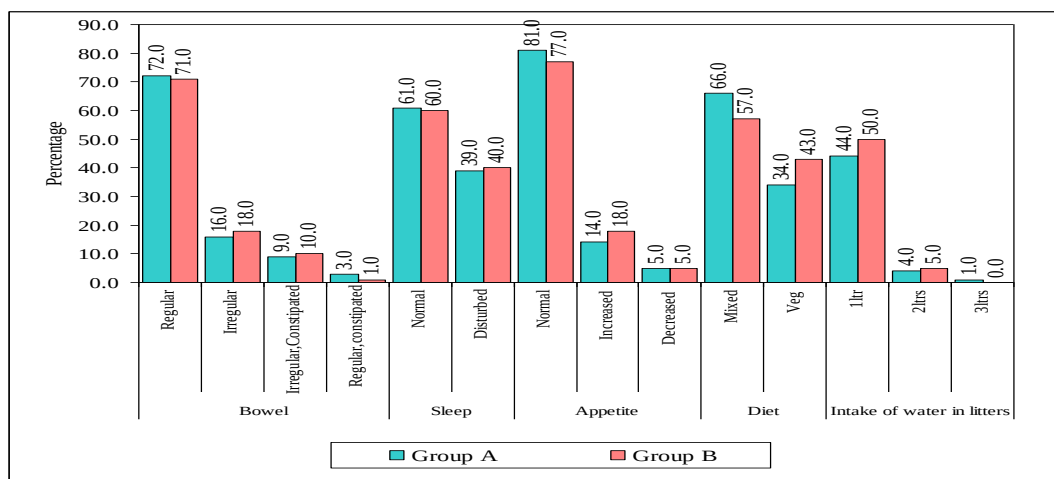


Table no.36: Showing physical activity wise distribution of patients.

Variables	STP		IATP		Total		χ^2	P value
Physical activity	N	%	n	%	n	%		
Highly Active	6	6.00	5	5.00	11	5.50	2.4630	0.2920
Moderate	50	50.00	61	61.00	111	55.50		
Sedentary	44	44.00	34	34.00	78	39.00		

Overall, most subjects had moderate physical activity (55.5%). Group wise distribution revealed that, moderate (50% in STP and 61% in IATP) to sedentary physical activity (61% in STP and 34% in IATP) was observed in both the groups (p=0.29). Between the groups, this observation was comparable (p=0.29).

Table no.37: Showing mental stress wise distribution of patients.

Variables	STP		IATP		Total		χ^2	P value
Mental stress	N	%	n	%	n	%		
Not Much	61	61.00	58	58.00	119	59.50	5.1280	0.0770
Moderate	39	39.00	37	37.00	76	38.00		
Calm	0	0.00	5	5.00	5	2.50		

The distribution of subjects based on mental status revealed that the majority did not have any psychological conditions i.e 61% in STP and 58% in IATP.

Table no.38: Showing emotional status wise distribution of patients.

Variables	STP		IATP		Total		χ^2	P value
Emotional status	N	%	n	%	n	%		
Calm	64	64.00	56	56.00	120	60.00	8.9500	0.0620
Tension	21	21.00	35	35.00	56	28.00		
Anxiety	11	11.00	5	5.00	16	8.00		
Anger	2	2.00	4	4.00	6	3.00		
Irritation	2	2.00	0	0.00	2	1.00		

The distribution of subjects based on emotional status revealed that the majority had calm mental status i.e 64% in STP and 56% in IATP.

Graph no.6 Showing physical activity and mental status wise distribution of patients.

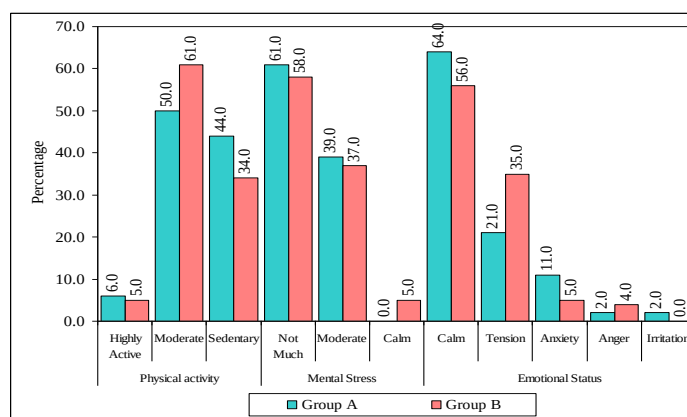


Table no.39: Habits wise distribution of the patient

Habits	STP		IATP		Total		χ^2	p-value
	N	%	n	%	n	%		
Smoking	22	22.00	19	19.00	41	20.50	0.2760	0.5990
Tobacco	5	5.00	6	6.00	11	5.50	0.0960	0.7560
Alcohol	22	22.00	27	27.00	49	24.50	0.6760	0.4110
Coffee	54	54.00	47	47.00	101	50.50	0.9800	0.3220
Tea	44	44.00	40	40.00	84	42.00	0.3280	0.5670

Habit wise distribution of subject reveals majority had habit of coffee intake (54% in STP and 47% in IATP) followed by tea intake (i.e 44% in STP and 40% in IATP)

Graph no.7: Habits wise distribution of the patient.

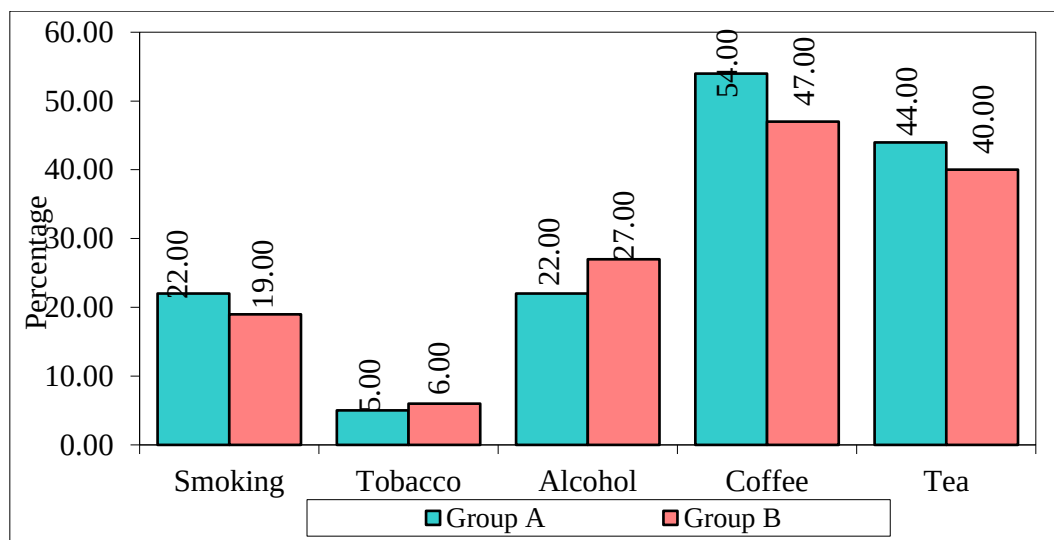


Table no.40: Built wise distribution of the patient.

Variables	STP		IATP		Total		χ^2	p-value
Built	N	%	N	%	n	%	3.1860	0.3640
Normal	23	23.00	19	19.00	42	21.00		
Thin	17	17.00	10	10.00	27	13.50		
Obese	19	19.00	21	21.00	40	20.00		
Moderate	41	41.00	50	50.00	91	45.50		
Total	100	100.00	100	100.00	200	100.00		

In STP, Majority had moderate built (41%) followed by normal built (23%) and in IATP, majority had moderate built (50%) followed by obese (21%).

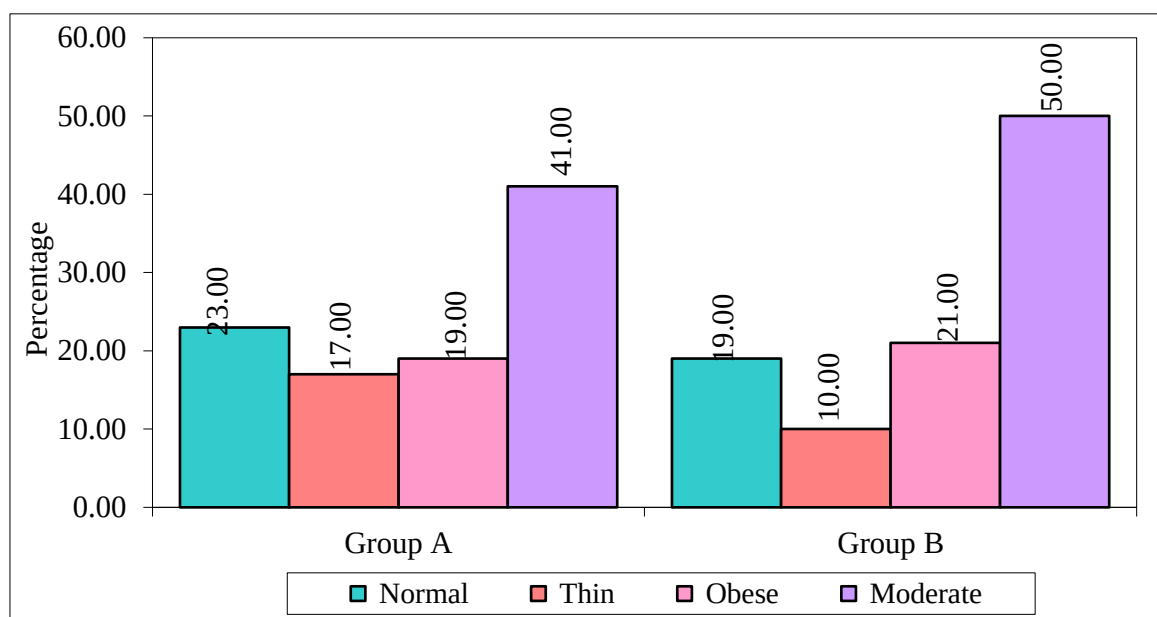
Graph no.08: Built wise distribution of the patient.

Table no.41: Prakruti wise distribution of the subjects

Variables	STP		IATP		Total		χ^2	p-value
Prakruti	N	%	N	%	n	%	0.8970	0.9250
VP	47	47.00	43	43.00	90	45.00		
VK	19	19.00	18	18.00	37	18.50		
PK	26	26.00	31	31.00	57	28.50		
KP	3	3.00	4	4.00	7	3.50		
PV	5	5.00	4	4.00	9	4.50		

Prakruti wise distribution of subjects revealed that, majority were *vata pitta prakrati* (47% in A and 43% in B) followed by *pitta kapha prakrati* (43% in STP and 31% in IATP).

Table no.42: Saara wise distribution of the patient

Variables	STP		IATP		Total		χ^2	p-value
Sara	N	%	N	%	n	%	8.7490	0.1200
Medasara	47	47.00	64	64.00	111	55.50		
Asthisara	26	26.00	19	19.00	45	22.50		
Mamsa sara	10	10.00	10	10.00	20	10.00		
Raktasara	7	7.00	4	4.00	11	5.50		
Rasasara	4	4.00	2	2.00	6	3.00		
Mamsa medasara	6	6.00	1	1.00	7	3.50		

In both the groups, majority had *Medasara* (47% in STP and 64% in IATP).

Table no.43: Comparison of STP and IATP with calories given in Kilocalorie (KCAL) by independent t test.

Variable	STP		IATP		t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.		
Calorie Given	1378.00	179.55	1332.00	163.84	1.8925	0.0599

Calorie calculation was done based on BMI and type of activity before administration of diet. Mean calorie administered in STP is 1378 kcal and in IATP is 1332 kcal.

Graph no.09: Comparison of STP and IATP with calorie Given in KCAL

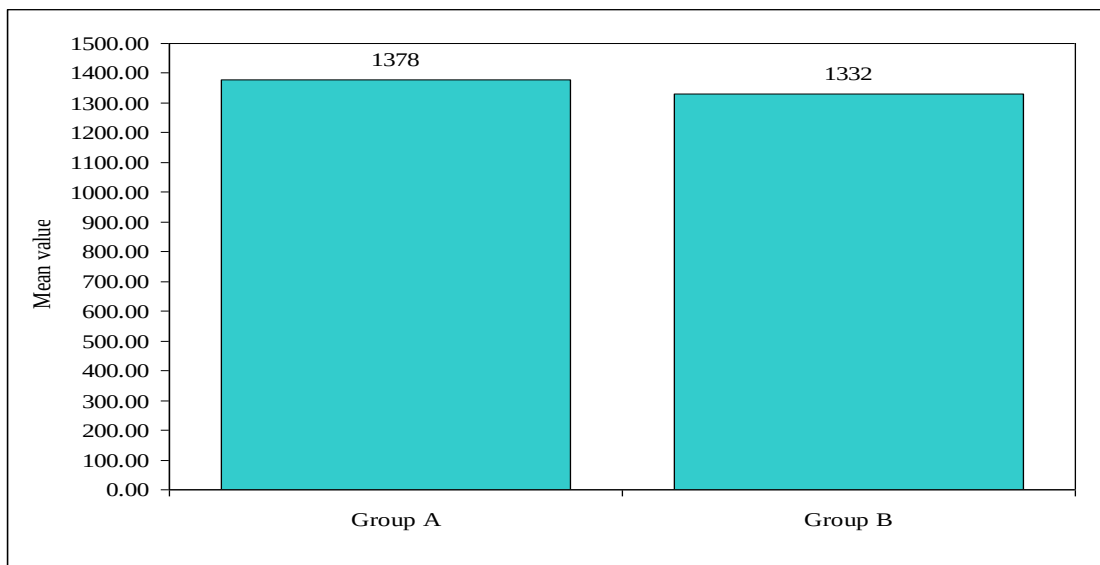


Table no.44: Comparison of STP and IATP with status of Adverse events

Adverse events	STP		IATP		Total	
	n	%	n	%	n	%
Total subjects	94	100	88	100	182	91
Nil	86	91.48	84	97.6	170	93
Constipation	0	0	2	2.27	2	1.1
Bloating	3	3.19	0	0	3	1.64
Diarrhea	2	2.12	2	2.27	4	2.19
Tremors	1	1.06	0	0	1	0.54
Hypoglycemia	2	2.12	0	0	1	0.54

Although no major adverse events in the study, there were minor adverse events i.e, two subjects in STP reported having diarrhea, three had blotting abdomen, two had hypoglycemia episodes, and one had an evening tremor. Two subjects in IATP had constipation, and two had diarrhea.

Table no.45: Comparison of STP and IATP with diet adherence, yoga, and exercise adherence by independent t test

Time points	STP		IATP		t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.		
Calorie Given	1378.72	177.12	1338.64	167.08	1.5682	0.1186

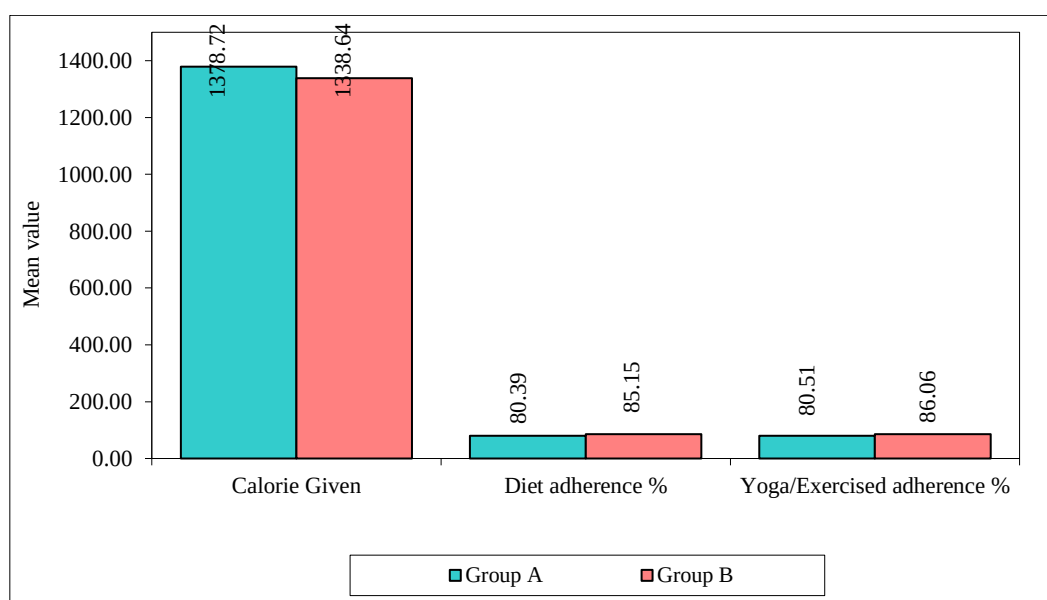
Diet adherence %	80.39	9.60	85.15	9.49	3.3576	0.0010*
Yoga/Exercised adherence %	80.51	9.93	86.06	9.96	3.7600	0.0002*

*p<0.05

Diet adherence (p=0.001) and exercise/yoga practice adherence (p=0.0002) were higher in IATP compared to STP.

Graph no.10: Comparison of STP and IATP with calorie given, diet adherence

%, Yoga/Exercised adherence %



6.2.3. Results

6.2.3. A. Anthropometric measures

Table no.46: Comparison of STP and IATP with weight in kg's before and after intervention using unpaired 't' test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
Weight	STP	0.62	1.24	0.13	-2.42	-3.14	-1.69	<0.0001***
	IATP	3.04	3.33	0.35				

*p<0.05

Study data indicates that, between the groups, weight reduction was more significant in IATP (p<0.001) than STP.

Table no.47: Comparison of weight in kgs in within STP and IATP paired 't' test.

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Weight (kg's)	STP	69.30±1 1.10	68.95±1 0.89	68.78±1 0.76	68.67±1 0.64	0.62	<0.001 ***
	IATP	71.43±1 2.86	70.01±1 1.86	69.28±1 1.40	68.39±1 1.03	3.04	<0.001 ***

*p<0.05

Both STP and IATP had a significant reduction in weight (in kg's) from before to after intervention (p<0.0001).

Graph no.11: Comparison of STP and IATP with weight in kgs at different treatment time points

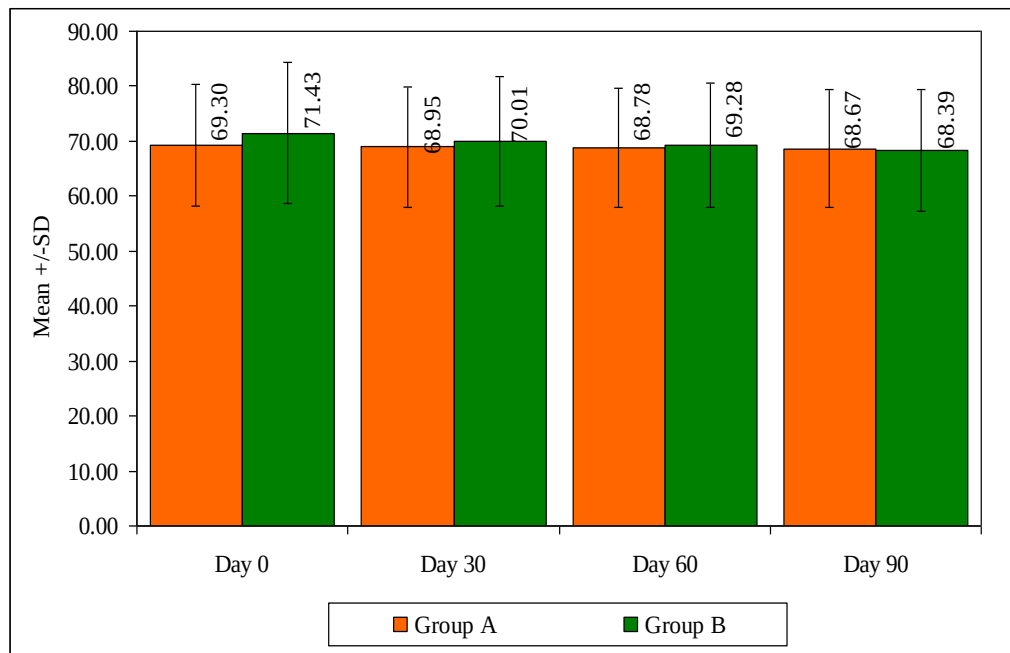


Table no.48: Comparison of STP and IATP with BMI at before and after intervention by unpaired 't' test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
BMI	STP	0.24	0.48	0.05	-0.92	-1.19	-0.64	<0.0001***
	IATP	1.16	1.26	0.13				

*p<0.05

Study revealed that, in BMI parameter, IATP had significant changes ($p < 0.001$) compared to STP (mean difference: -0.92, 95% CI: -1.19 to -0.64).

Table no.49: Comparison of different treatment time points with BMI in STP and IATP by paired 't' test.

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
BMI	STP	25.94±3.87	25.81±3.77	25.73±3.71	25.70±3.65	0.24	<0.001 ***
	IATP	26.88±4.98	26.36±4.62	26.06±4.39	25.72±4.28	1.16	<0.001 ***

*p<0.05

Within the group, both STP and IATP showed statistical significance in BMI measures (p<0.001)

Graph no.12: Comparison of STP and IATP with BMI at different treatment time points

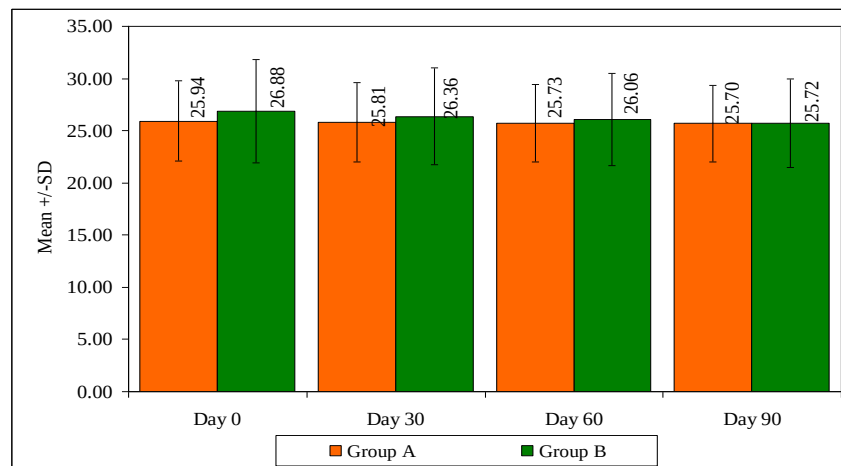


Table no.50: Comparison of STP and IATP with waist circumference in cm before and after intervention using unpaired ‘t’ test

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
Waist Circumference in CM	STP	0.54	0.93	0.10	-1.29	-1.73	-0.85	<0.001***
	IATP	1.83	1.93	0.21				

*p<0.05

The effect of the intervention on waist circumference between the group showed that IATP group is better (p<0.001) than the STP with a mean difference of -1.29, 95% CI of -1.73 to -0.85.

Table no.51: Comparison of different treatment time points with waist circumference in cm in STP and IATP by paired ‘t’ test.

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Waist circumference (cm)	STP	87.01±9.2	86.68±9.77	86.51±9.62	86.47±9.55	0.54	<0.001***
	IATP	89.43±10.71	88.47±10.26	88.04±10.11	87.60±9.97	1.84	<0.001***

*p<0.05

Within the group, both STP (p<0.001) and IATP (p<0.001) showed significant results.

Graph no.13: Comparison of STP and IATP with waist circumference in cm at different treatment time points

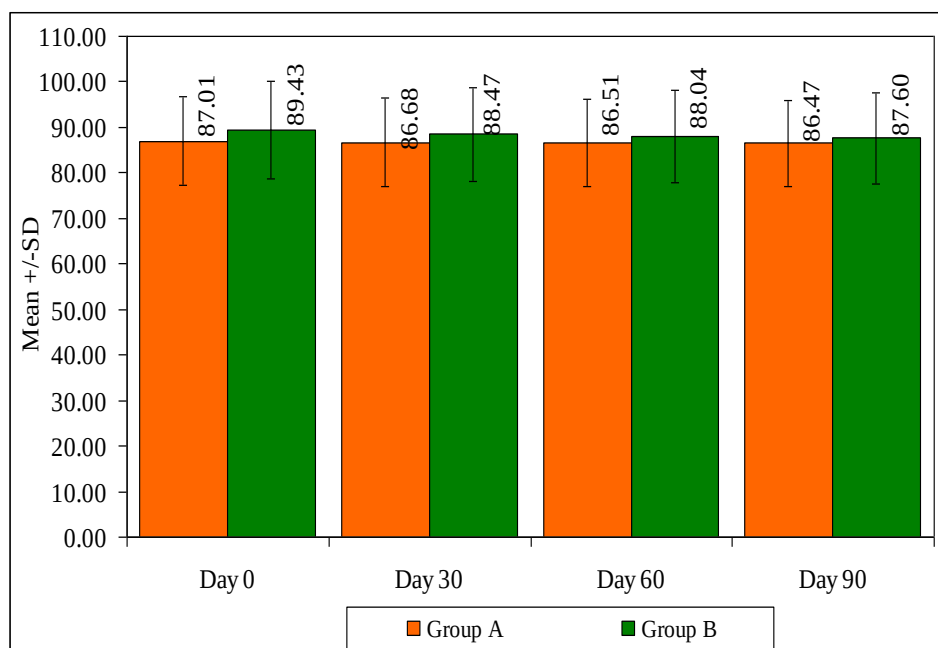


Table no.52: Comparison of STP and IATP with Body fat (%) at different treatment time points by unpaired t test

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
Body fat Index (%)	STP	0.59	0.73	0.08	-1.15	-1.63	-0.66	<0.0001***
	IATP	1.73	2.26	0.24				

*p<0.05

The impact of the intervention on whole body fat % between the groups showed that IATP had a significant outcome ($p < 0.001$) than STP (mean difference: -1.15, 95% CI: -1.63 to -0.66).

Table no.53: Comparison of different treatment time points with Body fat (%) in STP and IATP by paired t test

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Whole body fat percent (%)	STP	31.41±4.30	-	-	30.82±4.42	0.59	<0.001** *
	IATP	31.29±3.65	-	-	29.55±4.55	1.73	<0.001** *

*p<0.05

Both STP and IATP had significant reduction in body fat (%) from baseline to the 90th day of the intervention (p<0.001).

Graph no.14: Comparison of STP and IATP with Body fat (%) at different treatment time points

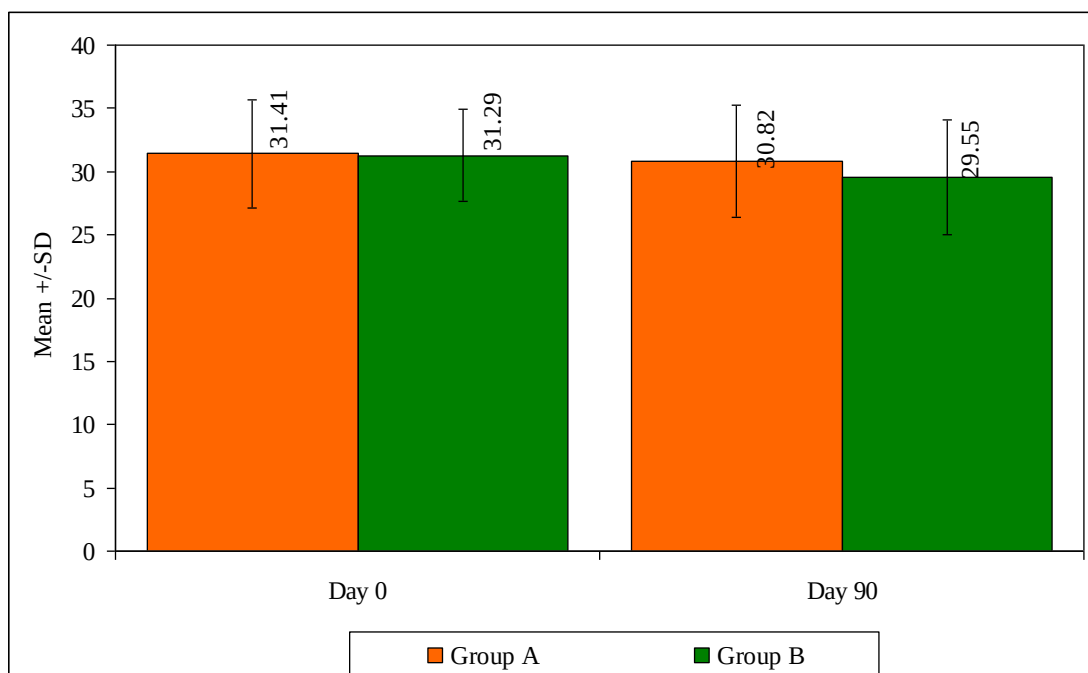


Table no.54: Comparison of STP and IATP with visceral fat (%) at before and after intervention with paired 't' test

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
Visceral Fat %	STP	0.34	0.78	0.08	-1.26	-1.75	-0.76	<0.001***
	IATP	1.60	2.30	0.24				

*p<0.05

The study's findings show that, on visceral fat IATP had a significant outcome (p<0.001) than STP (mean difference: -1.26, 95% CI: -1.75 to -0.76).

Table no.55: Comparison of different treatment time points with visceral fat (%) in STP and IATP by paired 't' test

Parameters	Intervention	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Visceral fat percent (%)	STP	12.66±7.00	-	-	12.32±6.94	0.34	<0.001**
	IATP	14.74±7.07	-	-	13.14±6.48	1.60	<0.001**

*p<0.05

Within the group analysis of visceral fat before and after intervention revealed that, both groups showed statistical significance (p<0.001).

Graph no.15: Comparison of STP and IATP with visceral fat (%) at different treatment time points

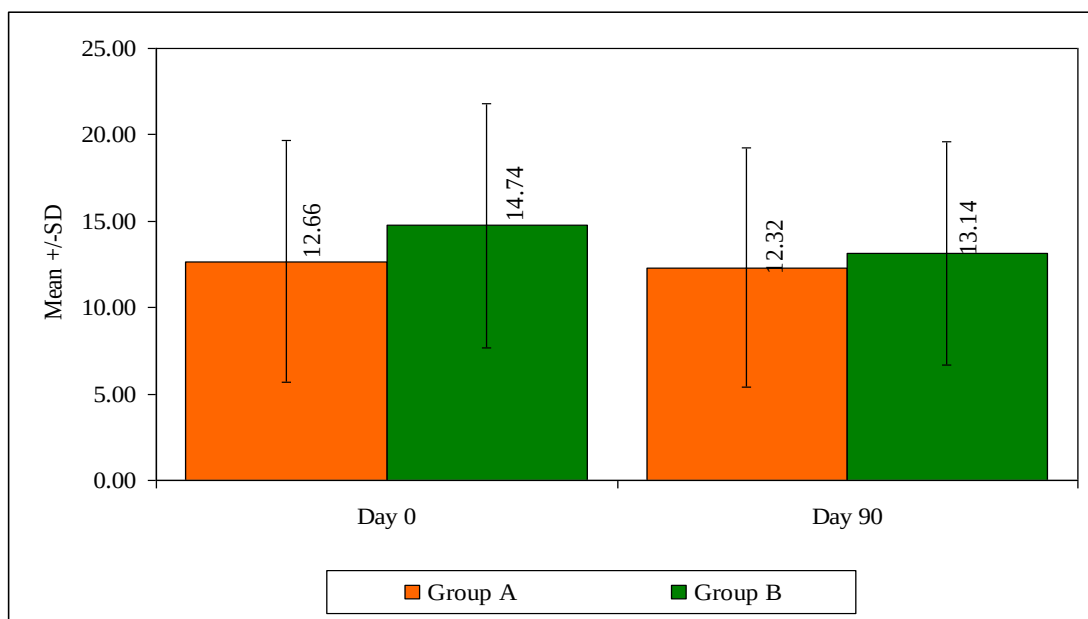


Table no.56: Comparison of STP and IATP with Body Surface Area at different treatment time points by unpaired 't' test

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
Body Surface Area	STP	0.01	0.05	0.00	-0.05	-0.09	-0.02	0.005
	IATP	0.07	0.18	0.02				

*p<0.05

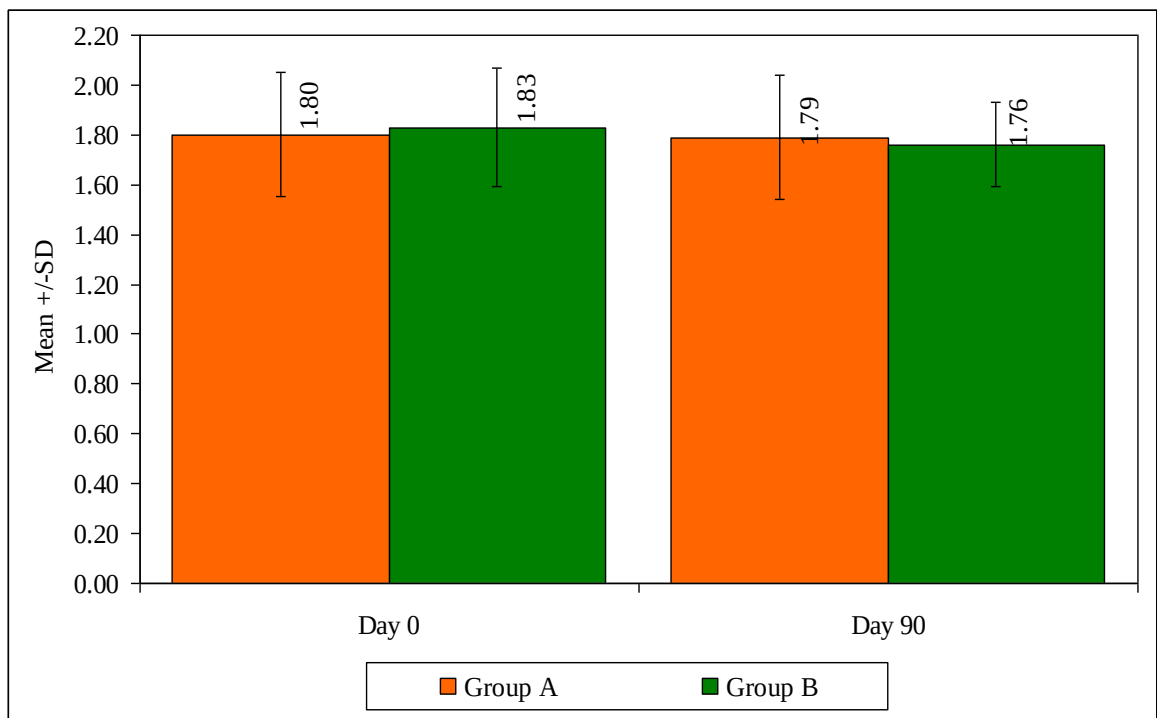
The results of the intervention on body surface area between the groups showed that group IATP had significant changes ($p=0.005$) than STP (mean difference: -0.05, 95% CI: -0.09 to -0.02).

Table no.57: Comparison of different treatment time points with Body Surface**Area in STP and IATP by paired t test**

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Body surface area(m ²)	STP	1.80±0.25	-	-	1.79±0.25	0.01	0.01*
	IATP	1.83±0.24			1.76±0.17	0.07	0.001**

*p<0.05

Statistical analysis within the group on body surface area shows that, both STP (p=0.01) and IATP (p=0.001) groups showed significant improvement.

Graph no. 16: Comparison of STP and IATP with Body Surface Area at different treatment time points

6.2.3. B. Hematological parameter

Table no.58: Comparison of STP and IATP with hemoglobin (HB) in % before and after intervention by unpaired 't' test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
HB in %	STP	-0.09	0.72	0.07	-0.12	-0.38	0.14	0.372
	IATP	0.03	1.07	0.11				

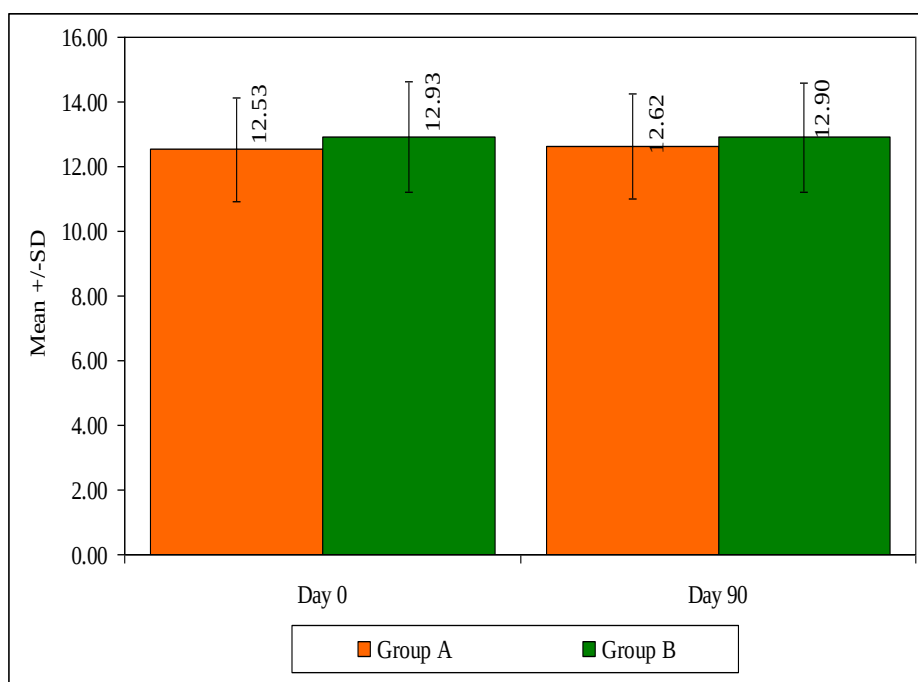
Result of intervention on Hb% before and after intervention revealed that, there is comparable outcome between the group (p=0.372)

Table no.59: Comparison of HB in % within STP and IATP by paired 't' test

Parameters	Intervention n STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) a
		0 th day	30 th day	60 th day	90 th day		
Hemoglobin(g/dl)	STP	12.53±1.60	-	-	12.62±1.62	-0.09	0.213
	IATP	12.93±1.71	-	--	12.90±1.69	0.03	0.81

The analysis of Hb% revealed there is no statistical significance in either of the groups.

Graph no.17: Comparison of STP and IATP with HB in % at different treatment time points



6.2.3.C. Glycemic parameter

Table no.60: Comparison of STP and IATP with HbA1C before and after intervention by unpaired 't' test

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
HbA1C	STP	0.41	0.69	0.07	-1.04	-1.27	-0.80	<0.001
	IATP	1.44	0.91	0.10				

*p<0.05

The effect of the intervention on HbA1c showed a significant difference ($p < 0.001$) in between-group comparison, favoring group IATP (mean difference: -1.04, 95% confidence interval [CI]: -1.27 to -0.80).

Table no.61: Comparison of different treatment time points with HbA1C in STP and IATP by paired 't' test.

Parameter s	Intervention n STP/IATP	Mean± standard deviation (SD)				Change e (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
HbA1C (%)	STP	8.41±0.88	-	-	8.00±0.85	0.41	<0.001** *
	IATP	8.70±1.05	-	-	7.26±0.94	1.44	<0.001** *

Within the group comparisons, in HbA1c before and after intervention showed that there is a significant improvement ($p < 0.001$) in both groups

Graph no.18: Comparison of STP and IATP with HbA1C at different treatment time points

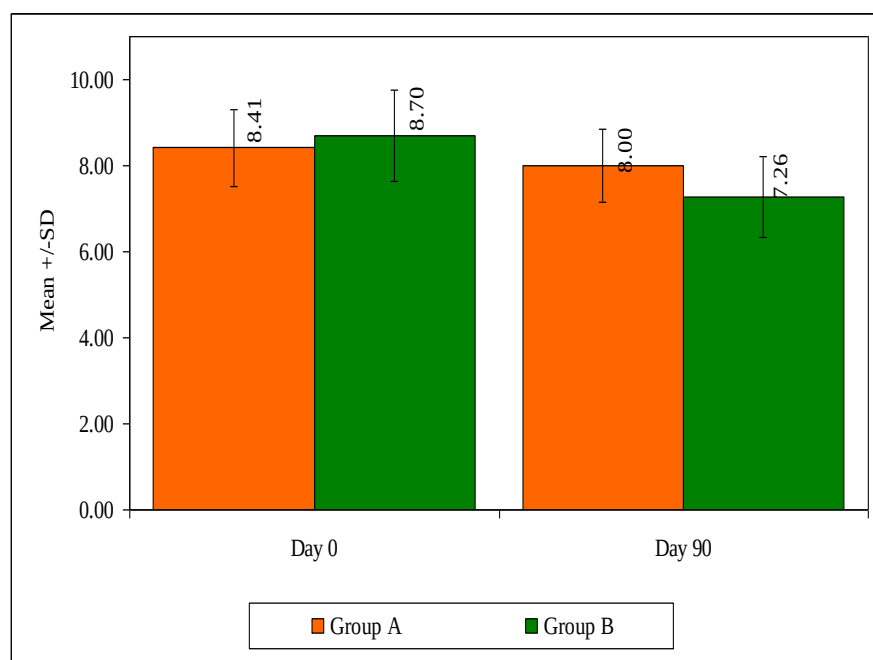


Table no.62: Comparison of STP and IATP with FBS at before and after intervention by unpaired ‘t’ test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P- Value
						Lower	Upper	
FBS	STP	16.72	46.38	4.78	-22.25	-42.10	-14.97	0.028*
	IATP	38.97	46.01	4.90				

*p<0.05

The impact of interventions between the group on FBS showed a significant difference (p=0.02) with better results in IATP (mean difference: -22.25, 95% CI: -42.10 to -14.97).

Table no.63: Comparison of different treatment time points with FBS in STP and IATP by paired ‘t’ test.

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
FBS (mg/dl)	STP	170.71±4 8.49	164.23±4 2.48	162.62±4 0.71	153.98±4 2.80	16.72	0.001* *
	IATP	173.57±5 2.50	145.77±3 6.79	135.03±2 9.50	134.60±3 8.71	38.97	<0.001 ***

*p<0.05

Results of intervention on FBS within the group revealed that, both STP (p=0.001) and IATP (p<0.001) showed significant results.

Graph no.19. Comparison of STP and IATP with FBS at different treatment time points

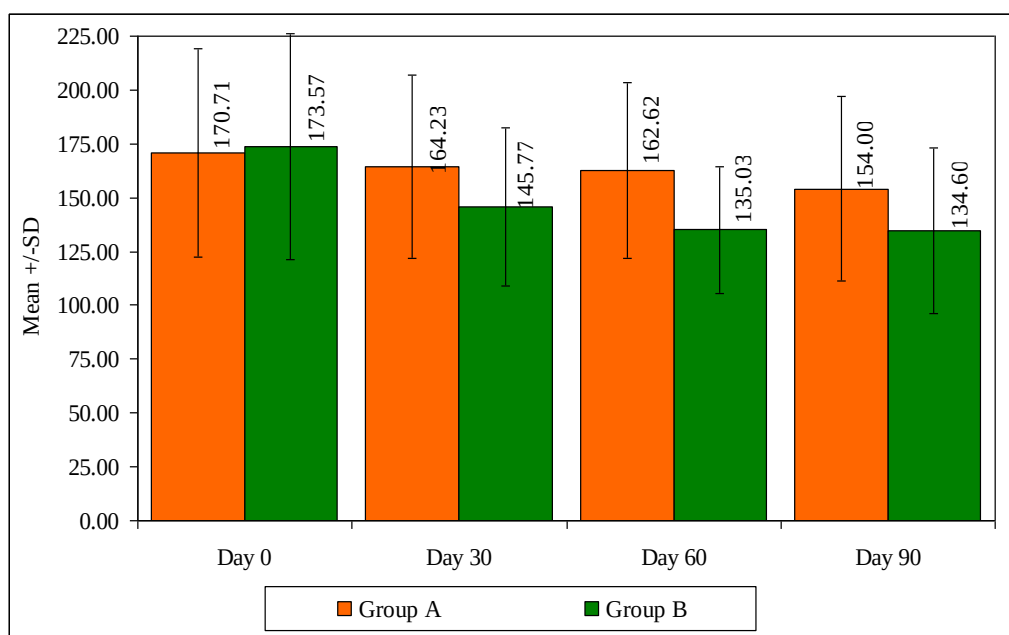


Table no.64: Comparison of STP and IATP with PPBS at different treatment time points by unpaired 't' test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
PPBS	STP	24.33	59.68	6.16	-52.27	-70.50	-34.05	<0.001***
	IATP	76.60	64.91	6.92				

*p<0.05

The result of the intervention on PPBG showed that group IATP had significant reduction ($p < 0.001$) than STP when compared between the groups (mean difference: -52.27, 95% CI: -70.50 to -34.05) .

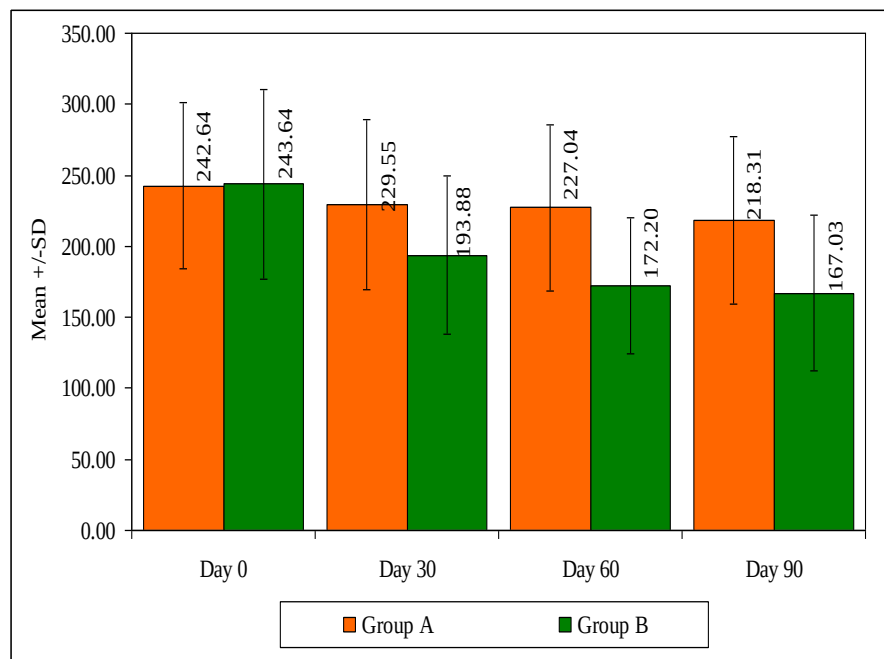
Table no.65: Comparison of different treatment time points with PPBS in STP and IATP by paired 't' test.

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
PPBG (mg/dl)	STP	242.64±5 8.61	229.55±5 9.98	227.04±5 8.14	218.31±5 8.83	24.33	<0.001 ***
	IATP	243.64±6 6.85	193.88±5 5.98	172.20±4 7.51	167.03±5 4.89	76.60	<0.001 ***

*p<0.05

Impact of intervention within the group in PPBS revealed that, both STP (p<0.001) and IATP (p<0.001) showed significant improvement.

Graph no.20: Comparison of STP and IATP with PPBS at different treatment time points



6.2.3. D. Insulin resistance parameter

Table no.66: Comparison of STP and IATP with Fasting Insulin in miU/L before and after intervention by unpaired ‘t’ test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
Fasting Insulin in mU/L	STP	2.36	6.95	0.72	-1.85	-4.48	0.79	0.168
	IATP	4.21	10.76	1.15				

*p<0.05

The result of the intervention on serum insulin revealed a comparable outcome between the group (p=0.168) with a mean difference of -1.85, 95% CI: -4.48 to 0.79.

Table no.67: Comparison of different treatment time points with Fasting Insulin in miU/L in STP and IATP by paired ‘t’ test.

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Fasting insulin(mIU/l)	STP	12.20±13.73	-	-	9.84±11.77	2.36	0.001**
	IATP	11.70±13.27	-	-	7.49±5.56	4.21	<0.001***

*p<0.05

Result of intervention in fasting insulin within the group showed that, both STP (p=0.001) and IATP (p<0.001) showed significant improvement

Graph no.21: Comparison of STP and IATP with Fasting Insulin in miU/L at different treatment time points

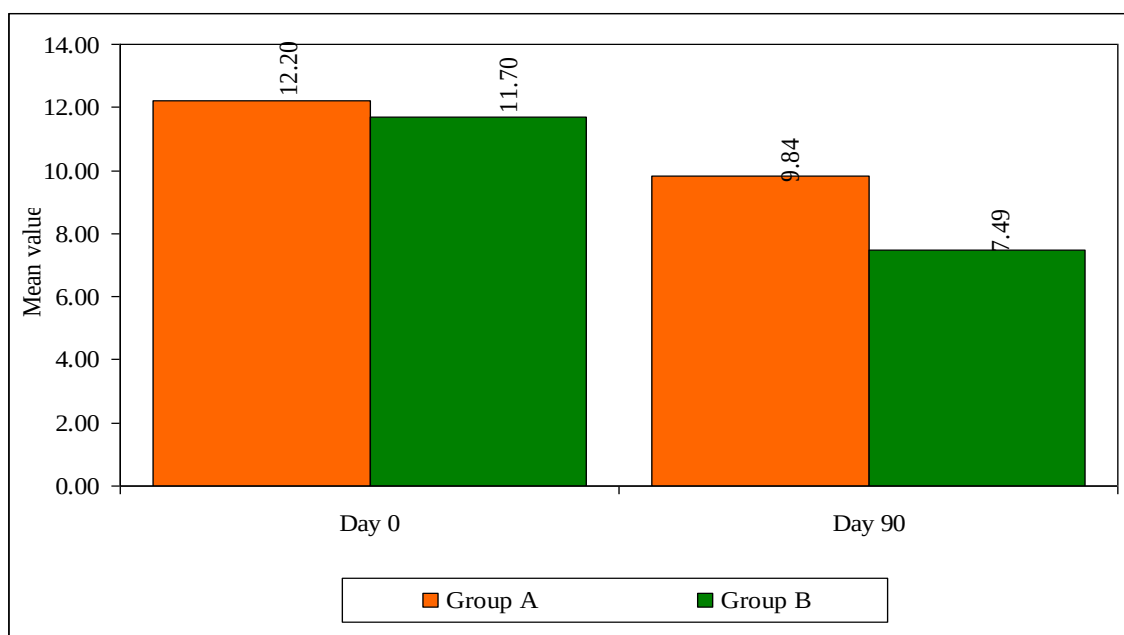


Table no.68: Comparison of STP and IATP with HOMA-IR before and after intervention by unpaired 't' test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
HOMA-IR	STP	0.93	2.66	0.27	-1.41	-2.40	-0.42	0.005
	IATP	2.33	3.99	0.43				

*p<0.05

The outcome of the intervention on HOMA IR between the groups showed a significant difference (p=0.005) revealing that IATP had greater improvement (mean difference: -1.41, 95% CI: -2.40 to -0.42).

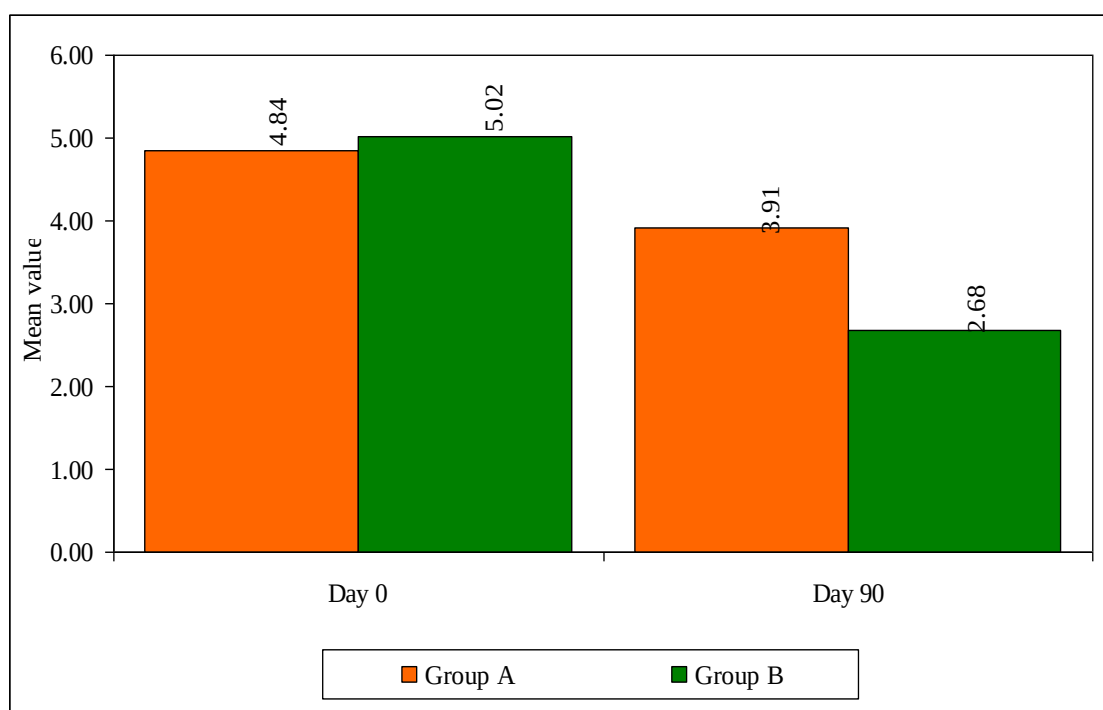
Table no.69: Comparison of different treatment time points with HOMA-IR in STP and IATP by paired ‘t’ test.

Parameter s	Intervention n STP/IATP	Mean± standard deviation (SD)				Change e (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Homa IR (in mg/dl)	STP	4.84±5.33	-	-	3.91±5.10	0.93	0.001**
	IATP	5.02±5.86	-	-	2.68±2.84	2.33	<0.001** *

*p<0.05

Effect of intervention on HOMA-IR within the group revealed that, both STP (p=0.001) and IATP (p<0.001) showed significant results.

Graph no.22: Comparison of STP and IATP with HOMA-IR at different treatment time points



6.2.3.E. Lipid profile

Table no.70: Comparison of STP and IATP with Total cholesterol (TC) before and after intervention unpaired ‘t’ test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
Total Chol	STP	3.10	21.97	2.27	-1.50	-7.23	4.24	0.607
	IATP	4.59	16.65	1.78				

*p<0.05

Result of intervention of total cholesterol, when compared between the groups, there are no significant differences (p=0.60) with a mean difference of -1.50, 95% CI: -7.23 to 4.24.

Table no.71: Comparison of different treatment time points with Total cholesterol in STP and IATP by paired ‘t’ test

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Total cholesterol(mg/dl)	STP	140.98±28.61	-	-	137.88±23.65	3.10	0.175
	IATP	144.44±26.42	-	-	139.85±21.65	4.59	0.01*

*p<0.05

Results of intervention on total cholesterol showed that, within the group, IATP showed significant improvement ($p=0.01$), whereas STP showed non-significant changes ($p=0.17$).

Graph no.24: Comparison of STP and IATP with Total cholesterol at different treatment time points

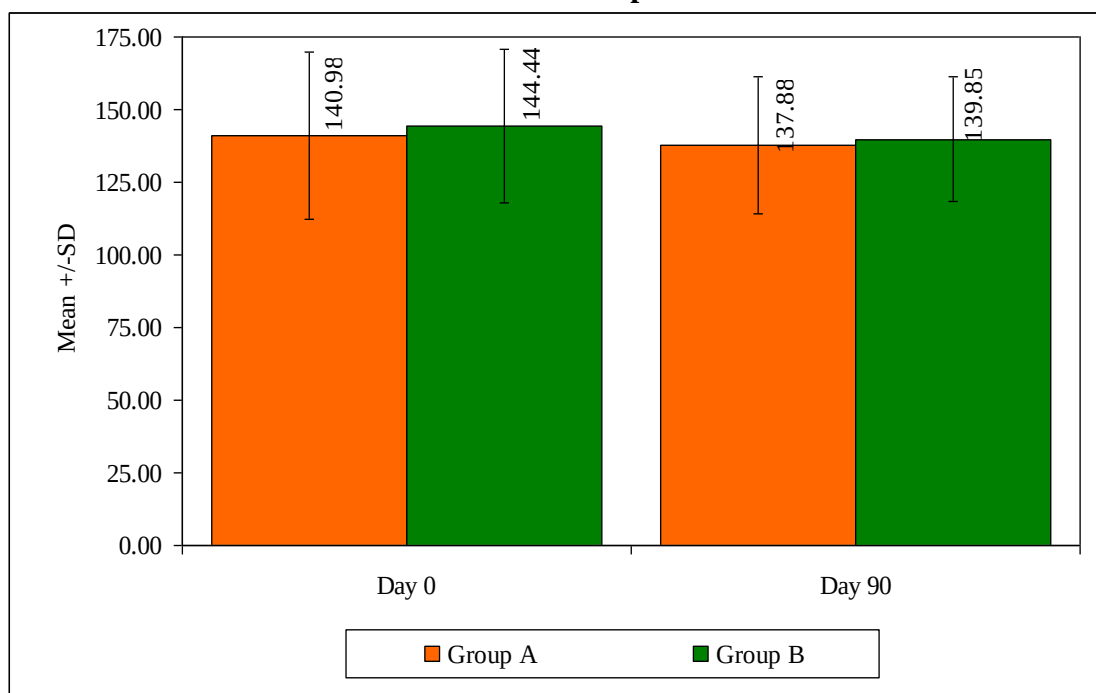


Table no.72: Comparison of STP and IATP with High density lipoprotein (HDL) before and after intervention by unpaired ‘t’ test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		p-Value
						Lower	Upper	
HDL	STP	-0.32	3.63	0.37	0.04	-0.97	1.06	0.931
	IATP	-0.36	3.30	0.35				

Result of intervention on HDL between the group Comparison showed non-significant results.

Table no.73: Comparison of different treatment time points with HDL in STP and IATP by paired 't' test.

Parameter s	Intervention n STP/IATP	Mean± standard deviation (SD)				Change e (BT-AT)	Sig(p) a
		0 th day	30 th day	60 th day	90 th day		
HDL	STP	44.30 ±3.85			44.62±4.70	0.32	0.396
	IATP	44.80±3.69			45.16±3.89	0.36	0.304

Comparison of different treatment time points with HDL in STP and IATP within the group was found to be non-significant.

Graph no.24: Comparison of STP and IATP with HDL at different treatment time points

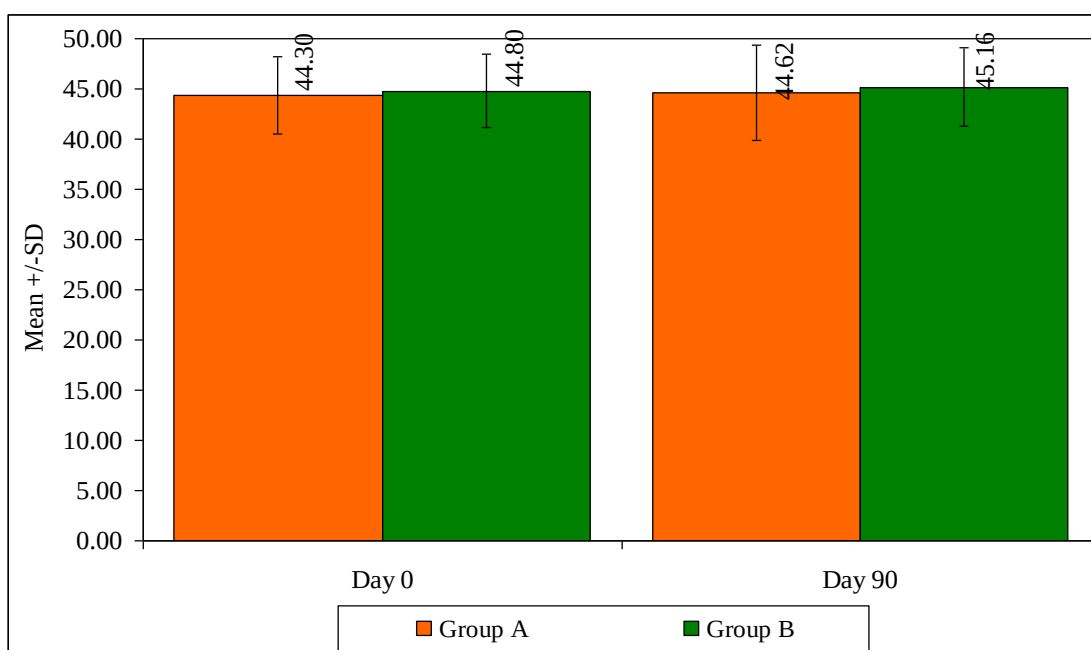


Table no.74: Comparison of STP and IATP with low density lipoprotein (LDL)
at before and after intervention by unpaired ‘t’ test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		p- Value
						Lower	Upper	
LDL	STP	2.55	20.58	2.12	0.59	-5.03	6.22	0.836
	IATP	1.95	17.64	1.88				

Result of intervention on LDL between the group comparison showed non-significant results.

Table no.75: Comparison of different treatment time points with LDL in STP
and IATP by paired ‘t’ test

Parameter s	Intervention n STP/IATP	Mean± standard deviation (SD)				Change e (BT- AT)	Sig(p) a
		0 th day	30 th day	60 th day	90 th day		
LDL	STP	65.50±22.19			62.95±19.70	2.55	0.23
	IATP	64.44±24.91			62.49±22.23	1.95	0.32

Comparison of different treatment time points with LDL in STP and IATP was found non-significant.

Graph no 25: Comparison of STP and IATP with LDL at different treatment time points.

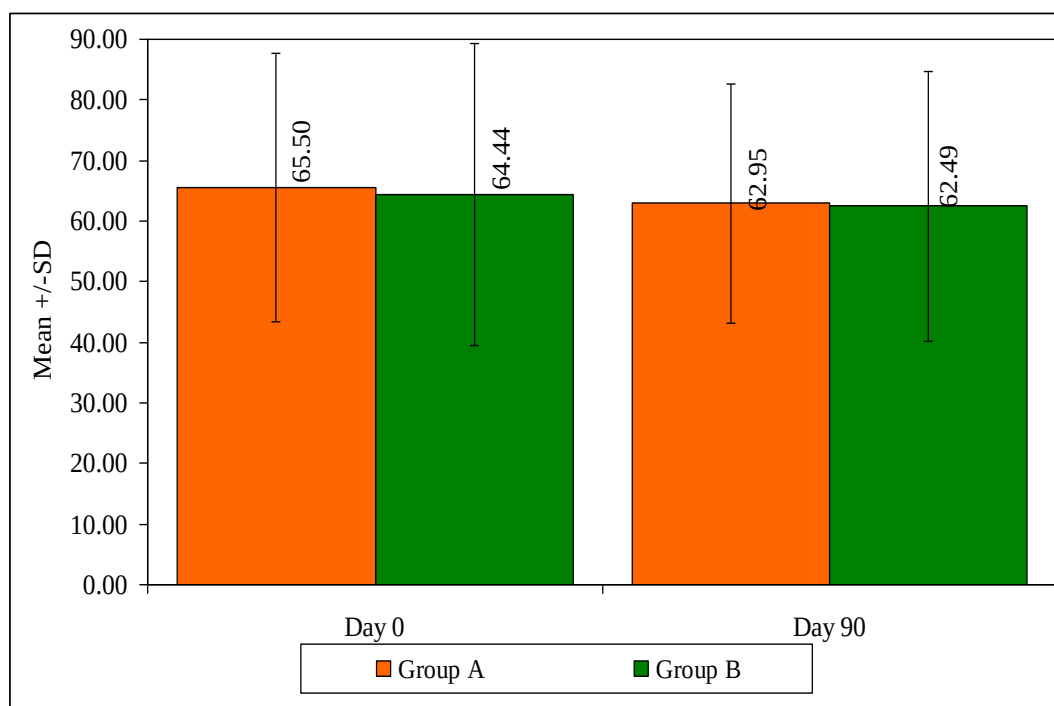


Table no.76: Comparison of STP and IATP with Very low-density lipoprotein (VLDL) at before and after intervention by unpaired 't' test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		p-Value
						Lower	Upper	
VLDL	STP	3.22	17.82	1.84	-1.45	-6.59	3.68	0.578
	IATP	4.67	17.25	1.84				

*p<0.05

The result of intervention on VLDL showed a non-significant difference between the group (p=0.57) with mean difference: -1.45, 95% CI: -6.59 to 3.68.

Table no.77: Comparison of different treatment time points with VLDL in STP and IATP by paired 't' test.

Parameter s	Intervention n STP/IATP	Mean± standard deviation (SD)				Change e (BT-AT)	Sig(p) a
		0 th day	30 th day	60 th day	90 th day		
VLDL (mg/dl)	STP	35.77±31.30	-	-	32.55±17.24	3.22	0.083
	IATP	36.20±18.85	-	-	31.54±21.25	4.67	0.01*

*p<0.05

Within the group, IATP showed significant results (p=0.01), whereas STP showed non-significant improvement (p=0.08)

Graph no.26: Comparison of STP and IATP with VLDL at different treatment time points

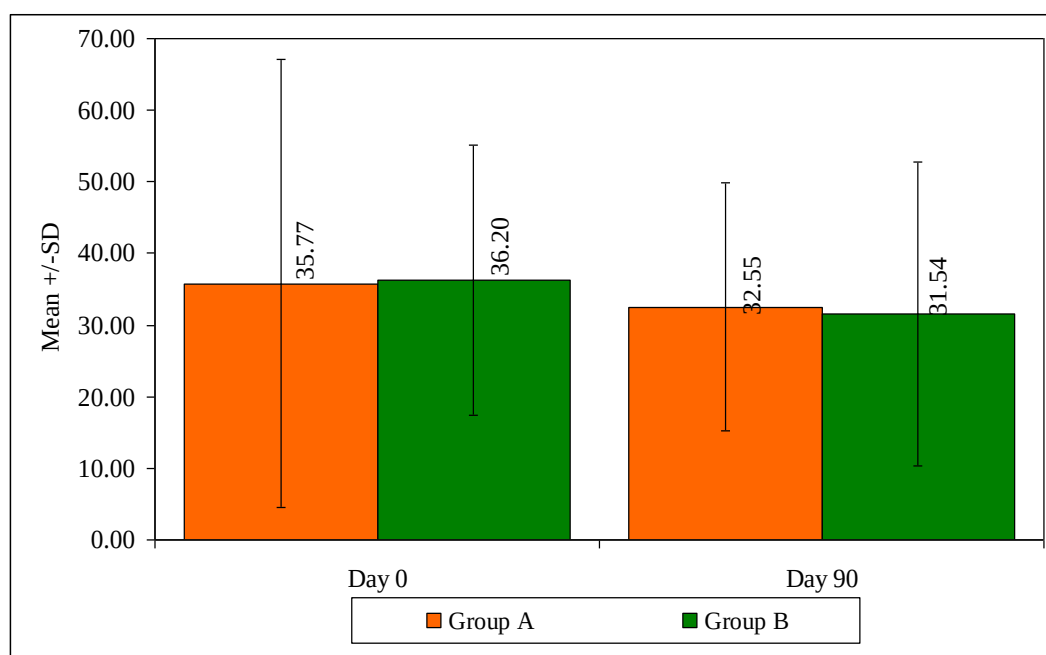


Table no.78: Comparison of STP and IATP with Sr Triglycerides before and after interventions by unpaired 't' test.

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	95% Confidence Interval of the Difference		P-Value
						Lower	Upper	
Sr Triglycerides	STP	10.61	41.64	4.29	-25.21	-42.30	-8.12	0.004
	IATP	35.82	72.11	7.69				

*p<0.05

In serum triglycerides, when compared between the groups, IATP showed significant changes (p=0.004) than STP (mean difference: -25.21, 95% CI: -42.30 to -8.12).

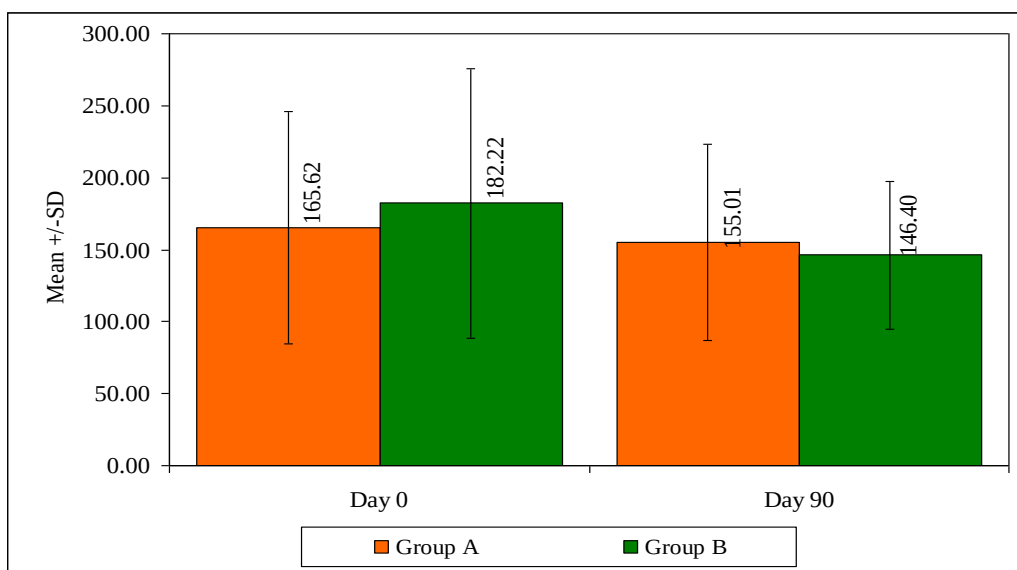
Table no.79: Comparison of different treatment time points with Sr Triglycerides in STP and IATP by unpaired 't' test

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Triglycerides(mg/dl)	STP	165.62±80.72	-	-	155.01±68.30	10.61	0.01*
	IATP	182.22±93.83	-	-	146.40±51.29	35.82	<0.001**

*p<0.05

Within the group, both STP (p=0.01) and IATP (p<0.001) had significant effects. The severity decreased from borderline triglyceride level (T: 182 mg/dl) to normal triglyceride level (T: 142 mg/dl) in IATP group.

Graph no.27: Comparison of STP and IATP with Sr Triglycerides at different treatment time points



6.2.3.F: Safety profile

Table no 80: Comparison of STP and IATP with Sr Creatinine at different treatment time points by unpaired ‘t’ test

Variable	Group	Mean Change in Parameter	SD	SE	Mean Difference	P-Value
Sr Creatinine	STP	0.04	0.08	0.01	-0.01	0.474
	IATP	0.05	0.09	0.01		

Effect of therapy on serum creatinine showed comparable outcome between the group (p=0.47).

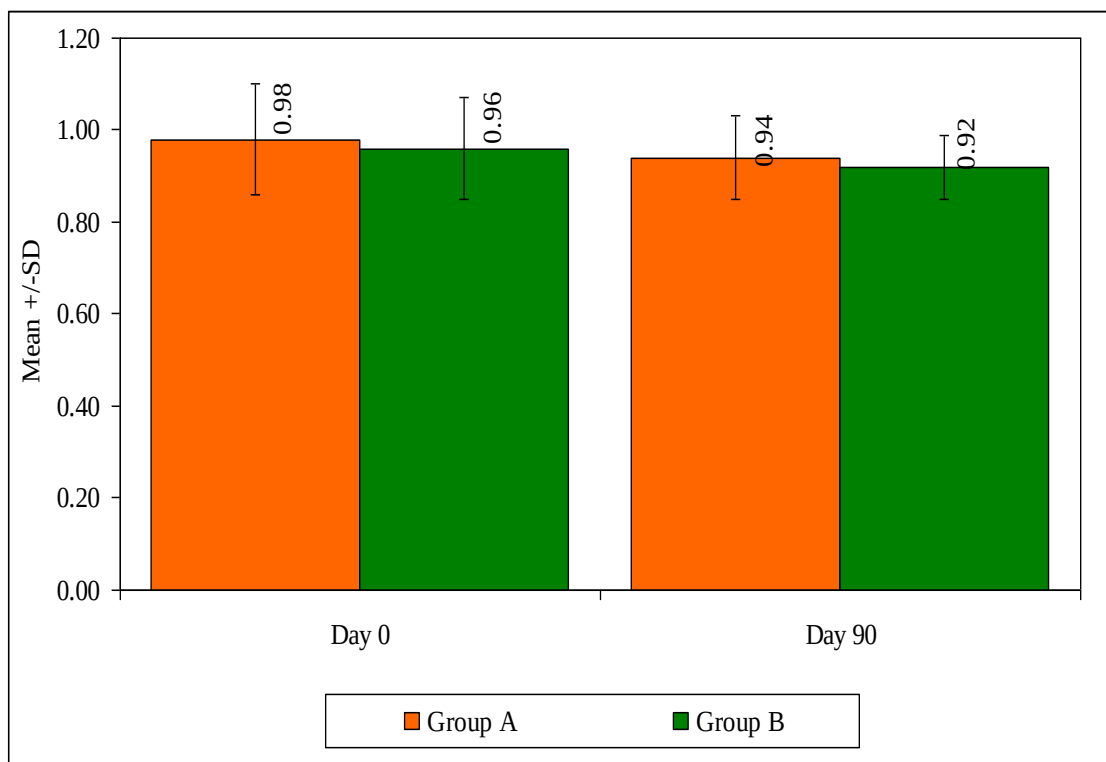
Table no.81: Comparison of different treatment time points with Sr Creatinine in STP and IATP by paired 't' test

Parameters	Intervention STP/IATP	Mean± standard deviation (SD)				Change (BT-AT)	Sig(p) ^a
		0 th day	30 th day	60 th day	90 th day		
Serum creatinine (mg/dl)	STP	0.98±0.12	-	-	0.94±0.09	0.04	<0.001***
	IATP	0.96±0.11	-	-	0.92±0.07	0.05	<0.001***

*p<0.05

Comparison of different treatment time points with serum creatinine within the group revealed that both STP and IATP showed significant changes (p<0.001).

Graph no.28: Comparison of STP and IATP with Sr Creatinine at different treatment time points



6.2.3.G. Diabetes QOL

Table no.82: Comparison of STP and IATP with satisfaction scores at different treatment time points by unpaired 't' test

Time points	STP		IATP		Cohen's d	t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.			
Day 0	49.57	6.28	48.80	7.48	0.11	0.7630	0.4464
Day 30	41.26	7.91	30.47	8.68	1.30	8.7717	0.0001*
Day 60	39.00	8.48	27.53	8.09	1.38	9.3194	0.0001*
Day 90	38.55	8.94	26.61	8.02	1.41	9.4621	0.0001*
Day 0 to Day 30	8.32	6.23	18.33	9.77	-1.25	-8.2960	0.0001*
Day 0 to Day 60	10.57	7.04	21.26	9.60	-1.28	-8.6005	0.0001*
Day 0 to Day 90	11.02	7.73	22.18	9.16	-1.32	-8.8992	0.0001*

*p<0.05

The effect of intervention on satisfaction score showed a significant difference (p=0.0001) favoring the IATP.

Table no.83: Comparison of different treatment time points with satisfaction scores in STP and IATP by paired t test

Groups	Changes from	Mean Diff	SD Diff.	% of change	t-value	p-value	Effect size
STP	Day 0 to Day 30	8.32	6.23	16.78	93.0000	0.0986	0.29
	Day 0 to	10.57	7.04	21.33	14.5665	0.0001*	1.43

	Day 60						
	Day 0 to Day 90	11.02	7.73	22.23	13.8173	0.0001*	1.45
IATP	Day 0 to Day 30	18.33	9.77	37.56	17.6068	0.0001*	2.27
	Day 0 to Day 60	21.26	9.60	43.57	20.7668	0.0001*	2.73
	Day 0 to Day 90	22.18	9.16	45.46	22.7083	0.0001*	2.86

*p<0.05

Within the group analysis of parameter on satisfaction score revealed that both the groups had shown significance. The improvement in IATP was at all-time points of 30th, 60th and 90th day of intervention (p=0.0001). In the STP, improvement was seen on the 60th and 90th day of intervention (p=0.0001).

Graph no.29: Comparison of STP and IATP with satisfaction scores at different treatment time points

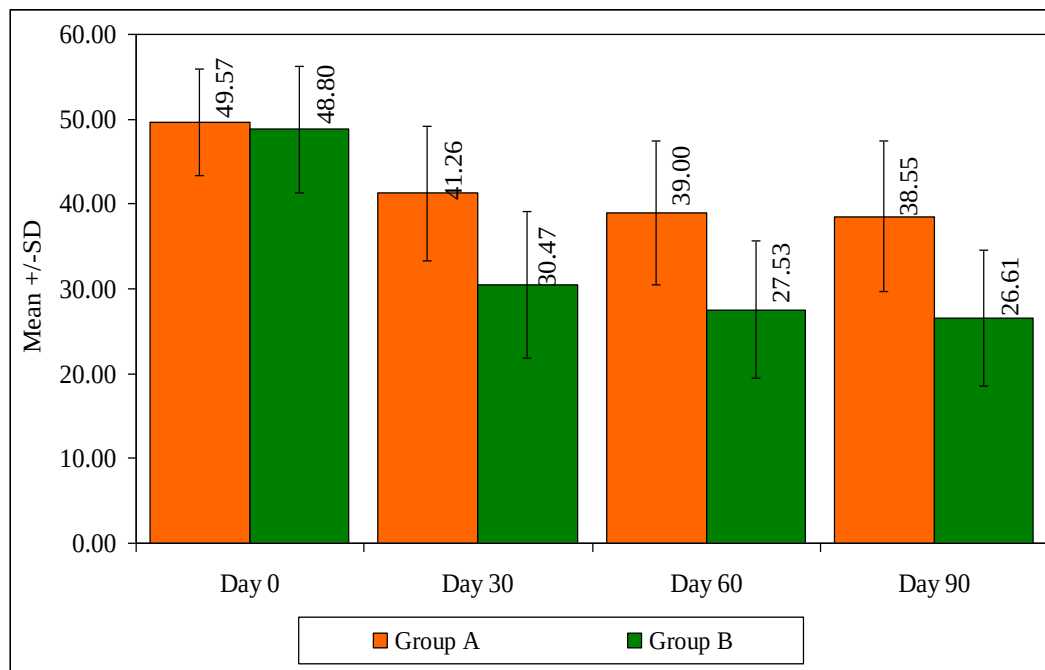


Table no.84: Comparison of STP and IATP with impact scores at different treatment time points by independent t test

Time points	STP		IATP		Cohen's d	t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.			
Day 0	56.36	7.84	50.69	9.86	0.64	4.3059	0.0001*
Day 30	46.86	9.07	35.22	9.03	1.29	8.6761	0.0001*
Day 60	44.89	9.67	31.10	8.79	1.49	10.0464	0.0001*
Day 90	44.40	10.22	30.03	8.96	1.50	10.0581	0.0001*
Day 0 to Day 30	9.50	7.01	15.48	12.04	-0.63	-4.1251	0.0001*
Day 0 to Day 60	11.47	8.61	19.59	9.90	-0.88	-5.9145	0.0001*
Day 0 to Day 90	11.96	9.17	20.66	10.73	-0.87	-5.8914	0.0001*

*p<0.05

The effect of intervention on impact score showed a significant difference (p=0.0001) favoring IATP.

**Table no.85: Comparison of different treatment time points with impact scores
in STP and IATP by paired t test**

Groups	Changes from	Mean Diff	SD Diff.	% of change	t-value	p-value	Effect size
STP	Day 0 to Day 30	9.50	7.01	16.86	93.0000	0.0986	0.28
	Day 0 to Day 60	11.47	8.61	20.35	12.9071	0.0001*	1.31
	Day 0 to Day 90	11.96	9.17	21.22	12.6380	0.0001*	1.32
IATP	Day 0 to Day 30	15.48	12.04	30.53	12.0626	0.0001*	1.64
	Day 0 to Day 60	19.59	9.90	38.65	18.5609	0.0001*	2.10
	Day 0 to Day 90	20.66	10.73	40.75	18.0568	0.0001*	2.20

*p<0.05

Within the analysis of parameter, impact score revealed that both the groups had shown significance. The improvement in IATP was at all-time points of 30th, 60th and 90th day of intervention (p=0.0001). In the IATP, improvement was seen on the 60th and 90th day of intervention (p=0.0001).

Table no.86: Comparison of STP and IATP with Concerns: Social/Vocational at different treatment time points by Mann-Whitney U test

Time points	STP			IATP			U-value	Z-value	p-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Day 0	7.53	2.45	88.88	8.26	3.70	94.30	3890.0	0.6912	0.4894
Day 30	7.41	1.80	91.29	7.38	1.41	91.73	4116.0	0.0549	0.9562
Day 60	7.41	1.80	92.21	7.33	1.36	90.74	4069.0	0.1872	0.8515
Day 90	7.41	1.80	92.21	7.33	1.36	90.74	4069.0	0.1872	0.8515
Day 0 to Day 30	0.12	0.76	86.17	0.89	2.83	97.19	3635.0	1.4092	0.1588
Day 0 to Day 60	0.12	0.76	86.14	0.93	2.94	97.23	3632.0	1.4176	0.1563
Day 0 to Day 90	0.12	0.76	86.14	0.93	2.94	97.23	3632.0	1.4176	0.1563

The concern domain (related to social/vocational) showed comparable results between the groups.

Graph 30: Comparison of STP and IATP with impact scores at different treatment time points

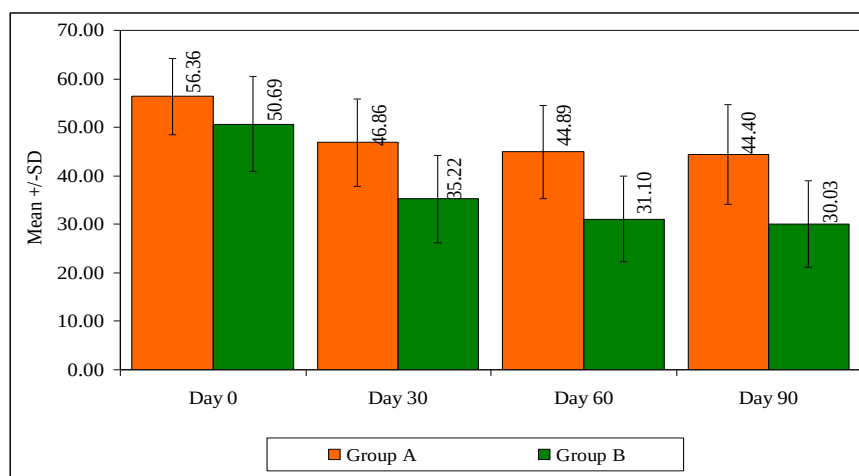


Table no.87: Comparison of different treatment time points with Concerns: Social/Vocational in STP and IATP by Wilcoxon matched pairs and Friedman's ANOVA test

Groups	Changes from	Mean Diff	SD Diff.	% of change	Z-value	p-value	Friedman's ANOVA	p-value
STP	Day 0 to Day 30	0.12	0.76	1.55	1.7748	0.0759	10.7142	0.0133*
	Day 0 to Day 60	0.12	0.76	1.55	1.7748	0.0759		
	Day 0 to Day 90	0.12	0.76	1.55	1.7748	0.0759		
IATP	Day 0 to Day 30	0.89	2.83	10.73	3.4078	0.0007*		
	Day 0 to	0.93	2.94	11.28	3.4078	0.0007*		

	Day 60						41.1170	0.0001*
	Day 0 to Day 90	0.93	2.94	11.28	3.4078	0.0007*		

* $p < 0.05$

In concern (social/vocational) domine, within the group result revealed that IATP improved at all-time points ($p=0.001$). In STP, improvement was not significant. The overall score demonstrated that there is a large difference between the groups ($p < 0.001$) with better improvement in the IATP group ($p < 0.001$).

Graph no.31: Comparison of STP and IATP with Concerns: Social/Vocational at different treatment time points

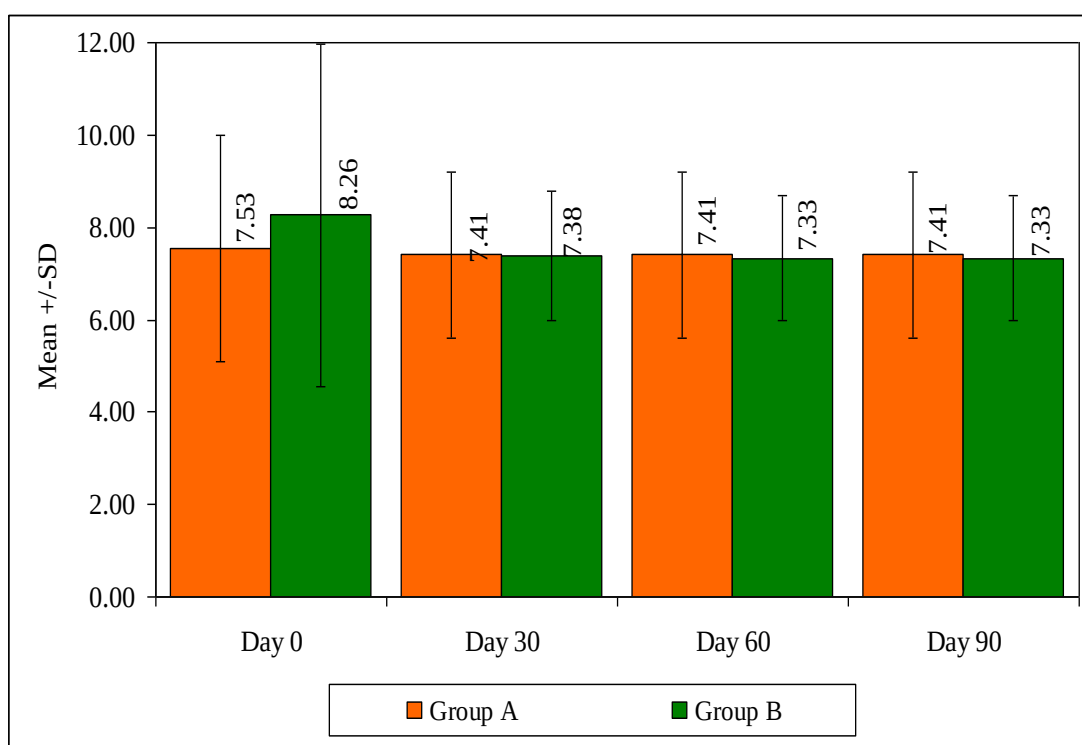


Table no.88: Comparison of STP and IATP with Concerns Related to DM at different treatment time points by Mann-Whitney U test.

Time points	STP			IATP			U-value	Z-value	p-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Day 0	8.79	2.38	92.99	8.58	2.40	89.90	3995.5	0.3942	0.6935
Day 30	7.53	2.22	105.62	6.35	1.83	76.42	2809.0	3.7348	0.0002*
Day 60	7.37	2.34	109.11	5.80	1.81	72.69	2480.5	4.6597	0.0001*
Day 90	7.31	2.33	109.14	5.74	1.81	72.66	2478.0	4.6667	0.0001*
Day 0 to Day 30	1.26	1.52	78.77	2.23	2.12	105.10	2939.5	3.3674	0.0008*
Day 0 to Day 60	1.41	1.64	75.62	2.78	2.34	108.47	2643.0	4.2022	0.0001*
Day 0 to Day 90	1.48	1.68	75.80	2.84	2.35	108.27	2660.5	4.1529	0.0001*

*p<0.05

The concern domain (related to DM) showed significant in IATP (p=0.0001)

Table no.89: Comparison of different treatment time points with Concerns Related to DM in STP and IATP by Wilcoxon matched pairs and Friedman's ANOVA test.

Groups	Changes from	Mean Diff	SD Diff.	% of change	Z-value	p-value	Friedman's ANOVA	p-value
STP	Day 0 to Day 30	1.26	1.52	14.29	6.3675	0.0001*	150.6950	0.0001*
	Day 0 to Day 60	1.41	1.64	16.10	6.4668	0.0001*		
	Day 0 to Day 90	1.48	1.68	16.83	6.4901	0.0001*		
IATP	Day 0 to Day 30	2.23	2.12	25.96	7.2082	0.0001*	193.6597	0.0001*
	Day 0 to Day 60	2.78	2.34	32.45	7.4748	0.0001*		
	Day 0 to Day 90	2.84	2.35	33.11	7.5248	0.0001*		

*p<0.05

In concern (related to DM) domine, within the group result revealed that both the groups showed significance at all time points (p=0.0001).

Graph no.33: Comparison of STP and IATP with Concerns Related to DM at different treatment time points.

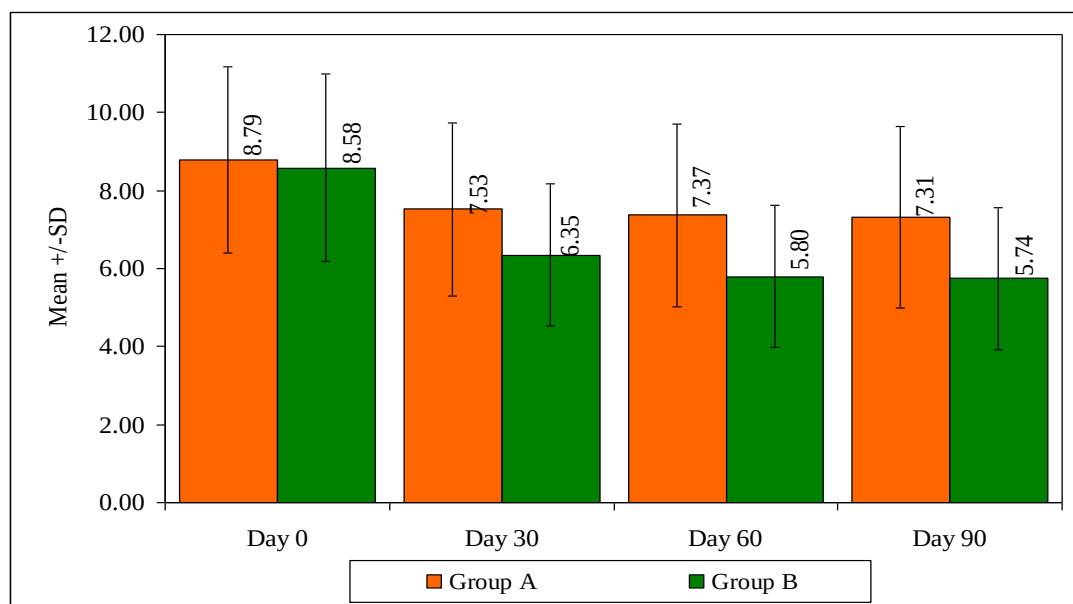


Table no.90: Comparison of STP and IATP with DM QOL total scores at different treatment time points by independent t test

Time points	STP		IATP		Cohen's d	t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.			
Day 0	122.34	13.48	118.03	14.87	0.30	2.0485	0.0420
Day 30	103.73	15.93	80.34	17.59	1.40	9.4117	0.0001*
Day 60	98.01	20.00	72.93	16.68	1.37	9.1527	0.0001*
Day 90	97.34	19.29	71.16	17.26	1.43	9.6266	0.0001*

Day 0 to Day 30	18.61	11.45	37.69	19.06	-1.25	8.2474	0.0001*
Day 0 to Day 60	24.33	16.27	45.10	18.04	-1.21	8.1647	0.0001*
Day 0 to Day 90	25.00	15.32	46.88	18.47	-1.29	8.7187	0.0001*

*p<0.05

The overall score of diabetes quality of life demonstrated that there is a large difference between the groups (p=0.0001).

Table no.91: Comparison of different treatment time points with DM QOL scores in STP and IATP by dependent t test

Groups	Changes from	Mean Diff	SD Diff.	% of change	t-value	p-value	Effect size
STP	Day 0 to Day 30	18.61	11.45	15.21	93.0000	0.0986	0.32
	Day 0 to Day 60	24.33	16.27	19.89	14.4945	0.0000	1.45
	Day 0 to Day 90	25.00	15.32	20.43	15.8226	0.0000	1.53
IATP	Day 0 to Day 30	37.69	19.06	31.93	18.5489	0.0000	2.32
	Day 0 to Day 60	45.10	18.04	38.21	23.4488	0.0000	2.86
	Day 0 to Day 90	46.88	18.47	39.71	23.8091	0.0000	2.92

*p<0.05

The overall score of diabetes quality of life within the group statistics revealed that there is better improvement in the IATP (p=0.0001).

Graph no.33: Comparison of STP and IATP with DM QOL total scores at different treatment time points

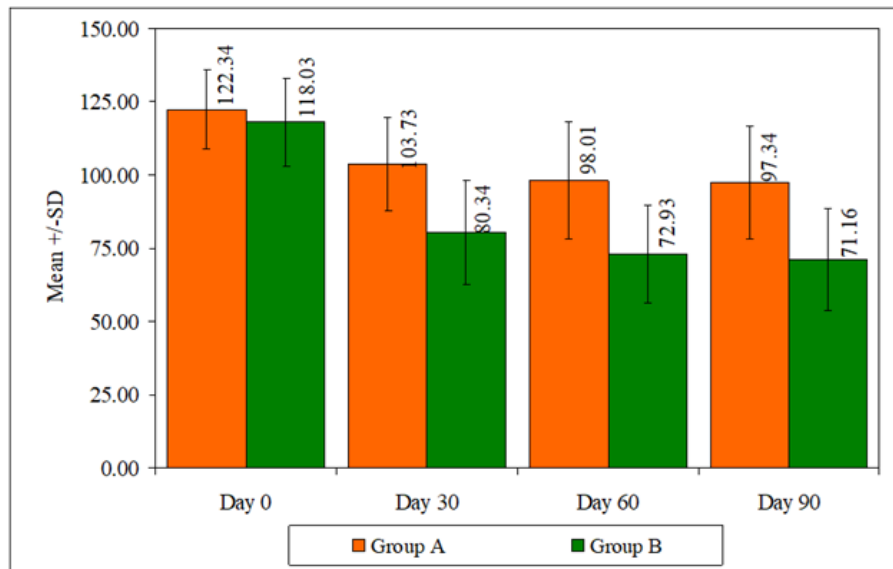


Table no.92: Effect on *Prameha purvaroop*a variables using Mann-Whitney U test (between the groups) and Wilcoxon matched pairs (within the group).

Si. no	Parameter	Intervention group	Baseline	30 th day	60 th day	90 th day	P value	Baseline (BL)-30 th day	BL-60 th day	BL-90 th day
1.	<i>Madhuryamasya</i>	STP	0.5±0.9	0.5±0.8	0.5±8	0.5±8	0.55	<0.05*	<0.05*	<0.05*
		IATP	0.7±0.9	0.50±8	0.40±7	0.40±7		<0.001*	<0.001*	<0.001*
2.	<i>Angashaitilya</i>	STP	1.5±1.0	1.4±10	1.4±10	1.41±0	<0.05*	0.1614	0.1097	0.35
		IATP	1.3±1.0	1.2±1.0	1.1±1.0	1.0±0.9		0.0010*	0.0001*	0.0001*
3.	<i>Alasya</i>	STP	1.7±0.8	1.4±0.8	1.3±0.8	1.3±0.8	0.0012*	0.0001*	0.0001*	0.0001*
		IATP	1.9±0.8	1.4±0.8	1.0±0.8	0.9±0.8		0.0001*	0.0001*	0.0001*

4.	Shitapriyatwa	STP	1.1± 0.9	1.0± 0.9	0.9± 0.9	0.9± 0.9	0.0011*	0.0117*	0.0003*	0.0002*
		IATP	0.9± 1.0	0.7± 0.8	0.5± 0.6	0.4± 0.6		0.0010*	0.0001*	0.0001*
5.	Angagandha	STP	1.1± 0.9	0.9± 0.8	0.8± 0.8	0.7± 0.8	0.0059*	0.0001*	0.0001*	0.0001*
		IATP	1.10. 9	0.80 .8	0.50. 7	0.40. 6		0.0001*	0.0001*	0.0001*
6.	Shramashwasa	STP	1.4± 0.9	1.2± 0.8	1.1± 0.9	1.1± 0.9	0.0001*	0.0022*	0.0001*	0.0001*
		IATP	1.3± 0.9	1.0± 0.8	0.5± 0.6	0.5± 0.6		0.0001*	0.0001*	0.0001*
7.	Swedadikyata	STP	1.5± 0.8	1.3± 0.8	1.1± 0.8	1.1± 0.8	0.0001*	0.0001*	0.0001*	0.0001*
		IATP	1.6± 0.8	1.3± 0.9	0.7± 0.8	0.6± 0.8		0.0001*	0.0001*	0.0001*
8.	Angasada	STP	1.7± 0.8	1.5± 0.8	1.3± 0.9	1.3± 0.8	0.0001*	0.0004*	0.0001*	0.0001*
		IATP	1.8± 0.7	1.4± 0.8	0.9± 0.8	0.8± 0.8		0.0001*	0.0001*	0.0001*

In this study, based on classical reference, assessment of clinical features of *prameha* was classified into two different parameters as *poorvaroopa* (premonitory symptoms) and *Rupa* (symptoms). *Poorvaroopa* assessment parameters included are *madhuryamasyata* (feeling sweetness in mouth), *angashaitilya* (flaccidity of muscles), *alasya* (indolence), *shitapriyatva* (desire for cold things), *angaganda* (body odour), *shramashwasa* (dysnoea on exertion), *swedadikyata* (perspiration) and *angasada* (physical fatigability).

Effect of intervention on *prameha poorvaroopa* outcome showed significant difference favoring IATP in *angashaitilya*, *alasya*, *shitapriyatva*, *angaganda*, *swedadikya* and *angasada* features. In *angashaitilya*, significant difference was observed on 60th (p=0.033) and 90th (p=0.010) day of intervention. In *alasya* changes were seen on 60th (p=0.019) and 90th (p=0.0012) day of intervention. In *anagaganda* also changes were seen on 60th (0.046) and 90th (0.005) day of intervention. In *shramashwasa* and *angasada*, statistical significance was observed on the 60th and 90th day of intervention (p=0.001). In *swedadikya*, difference was observed on 60th (p=0.0016) and 90th (p=0.0001). No difference was observed between the group in *madhuryamasya* but significant changes shown within the STP (p=0.0007) and IATP (p=0.0001).

Table no.93: Effect on *Prameha roopa* variables using Mann-Whitney U test (between the groups) and Wilcoxon matched pairs (within the group).

Si. no	Parameter	Intervention	Baseline	30 th day	60 th day	90 th day	P value	BL-30 th	BL-60 th day	BL-90 th day
1.	Mutra madhurya	STP	1.8 ± 2.0	1.6 ± 2.0	1.4 ± 1.0	1.3 ± 1.0	0.0001 *	0.0001*	0.0001*	0.0001 *
		IATP	2.0 ± 2.0	1.4 ± 1.0	0.8 ± 1.0	0.7 ± 0		0.0001*	0.0001*	0.0001 *
2.	Prabhuta Mutrata	STP	1.6 ± 1.0	1.3 ± 1.0	1.2 ± 1.0	1.1 ± 1.0	0.0001 *	0.0001*	0.0001*	0.0001 *
		IATP	1.6 ± 2.0	1.2 ± 1.0	0.6 ± 1.0	0.5 ± 0.0		0.0001*	0.0001*	0.0001 *

3.	Pipasaadhikya	STP	1.7 ±2. 0	1.4± 1.0	1.3± 1.0	1.2± 1.0	0.0001 *	0.0001*	0.0001*	0.0001 *
		IATP	1.8 ±2. 0	1.3± 1.0	0.8±1. 0	0.6± 0.0		0.0001*	0.0001*	0.0001 *
4.	Kshudhaadhikya	STP	1.7 ±2. 0	1.5± 2.0	1.3± 1.0	1.3± 1.0	0.0002 *	0.0001*	0.0001*	0.0001 *
		IATP	1.9 ±2. 0	1.6± 2.0	1.0± 1.0	0.8± 1.0		0.0001*	0.0001*	0.0001 *
5.	Klama	STP	1.5 ±1. 0	1.4± 1.0	1.3± 1.0	1.2± 1.0	0.0001 *	0.0117*	0.0001*	0.0001 *
		IATP	1.4 ±1. 0	1.1± 1.0	0.8± 1.0	0.7± 1.0		0.0001*	0.0001*	0.0001 *
6.	Purishabaddhat	STP	0.6 ±0. 0	0.5± 0.0	0.4± 0.0	0.3± 0.0	0.0252 *	0.0051*	0.0002*	0.0001 *
		IATP	0.6 ±0. 0	0.4± 0.0	0.2±0. 0	0.1±0. 0		0.0001*	0.0001*	0.0001 *

Impact of intervention on *Prameharoopa* parameter showed significant difference towards IATP in *mutramadhurya*, *prabhutamutrata*, *pipasa* from 60th day of intervention with $p = 0.0001$. In *Khsudadikyata*, the group comparison showed that, significance in IATP was found on 60th ($p=0.012$) and 90th day ($p=0.00021$). In *klama*, difference was observed between the group from 30th ($p=0.0156$), 60th ($p=0.0001$) to 90th ($p=0.0001$) day of intervention favoring IATP. In *Purishabaddata*, between the group comparison showed that, IATP was significant on 90th day ($p=0.0252$).

- **Safety profile**

- The significant changes observed in serum creatinine levels at different time points within both the STP and IATP groups ($p < 0.001$) suggest that these treatments have a measurable physiological impact on renal function. Importantly, the absence of adverse trends in serum creatinine levels throughout the treatment period supports the renal safety profile of the drugs.
- There were minor, non-serious adverse events reported in the study. In total, twelve individuals in this study reported mild adverse events. In STP group, eight subjects reported adverse events, in that two subjects had diarrhea, three experienced bloating, two had episodes of hypoglycemia, and one had an evening tremor. In IATP group, 4 subjects experienced mild adverse events, in that two participants experienced constipation, and two had diarrhea. These adverse effects did not require any additional interventions and subsided on their own. No major adverse events were reported in the study. There were no discontinuations or withdrawals due to adverse events.

Tab no 94: Showing Result Summary

Parameter	Within Group-A (STP) (Control group)			Within Group-B (IAT) (Trial group)			B/W Groups
	0-30	0-60	0-90	0-30	0-60	0-90	
Weight	-	-	***	-	-	***	Sig(B>A)
BMI	-	-	***	-	-	***	Sig(B>A)
Waist circumference	-	-	***	-	-	***	Sig(B>A)
Body surface area	-	-	*	-	-	**	Sig(B>A)
Visceral fat (%)	-	-	***	-	-	***	Sig(B>A)
Body fat (%)	-	-	***	-	-	***	Sig(B>A)
HbA1C	-	-	***	-	-	***	Sig(B>A)
FBS	-	-	***	-	-	***	NS
PPBS	-	-	***	-	-	***	Sig(B>A)
Serum Insulin	-	-	**	-	-	***	NS
HOMA-IR	-	-	**	-	-	***	Sig(B>A)

TC	-	-	NS	-	-	*	NS
HDL	-	-	NS	-	-	NS	NS
LDL	-	-	NS	-	-	NS	NS
VLDL	-	-	NS	-	-	*	NS
Triglycerides	-	-	*	-	-	***	*
Creatinine	-	-	***	-	-	***	NS
DQOL	***	***	***	***	***	***	***

Note: * P<0.05, **P<0.01, *P<0.001, NS: Non-significant**

7. DISCUSSION

The clinical study was carried out to evaluate the efficacy of Integrated *Ayurveda* treatment protocol in T2DM. Study design was Randomized Controlled Clinical Trial. A total of 200 patients were recruited in the study, 100 in each group. Patients in STP received Tab metformin ≥ 1000 mg/day along with standard dietary and lifestyle guidelines for 90 days. Patients in IATP received Tab metformin ≥ 1000 mg/day with add on *Ayurveda* intervention which include *Ayurveda* polyherbal formulation (*Madhumehari ghanavati*) 500 mg 2 tablets thrice daily after food with water along with *Ayurveda* diet and Yoga. The parameters HbA1C, insulin, Homa IR, Serum Creatinine and lipid profile were assessed on baseline and 90th day. The parameters FBG, PPBG, anthropometric parameter, and Diabetes quality of life were assessed on Baseline, 30th, 60th and 90th day of intervention.

Discussion is elaborated under following subheadings:

7.1. Discussion on Observation

7.2. Discussion on Results

7.1. Discussion on Observation

➤ Gender

- Males were in more in number in both the groups i.e., in STP (53%) and in IATP (54%). Between the groups, there was a comparable distribution.
- According to a study based on an ICMR project, there were no considerable variations in prevalence between men and women in the Indian scenario¹²³.

➤ **Religion**

- Maximum numbers of subjects recruited in the study were from Hindu religion in both the groups i.e. in STP (92%) and in IATP (86%). Between the groups, there was comparable distribution. As demography of area where study was conducted is predominant of Hindu religion.

➤ **Education status**

- In both the groups, the maximum number of subjects were graduates i.e., in STP (37%) and IATP (33%). While comparing the group, both have similar observation. [p=0.1310] Subjects from all categories of educational status were recruited indicating that prevalence is not strongly related to educational status.

➤ **Socio economic status**

- The maximum people belong to middle class group i.e. 75% in STP and 76% in IATP. Due to the demographic status of the area where study was conducted may have affected this distribution.

➤ **Occupation**

- Occupation wise distribution of subjects revealed that, majority (32% in STP and 35% in IATP) were homemakers followed by officers (29% in STP and 22% in IATP). Between the groups, there was comparable distribution (p=0.85).

➤ **Diet**

- The majority had mixed diet pattern (66% in STP and 57% in IATP) with a comparable distribution between the groups (p=0.19).

➤ **Lifestyle factors**

- A moderation (50% in STP and 61% in IATP) to sedentary lifestyle (61% in STP and 34% in IATP) was observed in both the groups ($p=0.29$). Between the groups, this observation was comparable ($p=0.29$). According to epidemiological research, those who are physically active are 30-50% less likely to acquire T2DM than those who are sedentary and less physically active¹²⁴.

➤ **Appetite**

- In both the groups, the majority (81% in STP, 77% in IATP) had a normal appetite. Between the groups, there was comparable distribution ($p=0.740$).

➤ **Sleep**

- The majority had normal sleep pattern (61% in STP and 60% in IATP) with a comparable distribution between the groups ($p=0.8850$).

➤ **Calorie intake**

- Calorie administered was nearly equal in both the group (above 1300 to below 1400 Kcal) with $p = 0.1186$.

➤ **Family history of T2DM**

- Among the total sample, the maximum population (60%) had family history of T2DM. Group wise distribution revealed, 56% had family history in STP and 44% in IATP. Between the groups, the distribution was similar ($p=0.24$). As per literature, there is a high risk with family history in the development of T2DM¹²⁵. Same observation was found in our study.

➤ **Habit wise distribution**

- The habit of intake of smoking, tobacco, alcohol, coffee, and tea did not predominate in any category.

➤ **Desha wise distribution**

- In both the groups, majority were *sadharana desha* (97% in STP and 99% in IATP). Due to the demographic status of the area where the study was conducted may have affected this distribution.

➤ **Built wise distribution.**

- Moderate (41%) to normal (23%) built in STP and moderate (50%) to obese (21%) built in IATP. Between the groups, comparable distribution was observed.

➤ **Prakrati wise distribution of patients**

- The majority were *VataPitta prakrati* i.e 47% in STP and 43% in IATP. Between the group, comparable observation ($p=0.9250$).

➤ **Sara wise distribution of patients.**

- In both groups, the majority were *medosara*. Between the groups, comparable changes were seen ($p=0.12$). Since *meda* is considered as prime *dushya* in the pathogenesis of *prameha* this distribution had been justified.

➤ **Age wise distribution**

- In age wise distribution, it was observed that in STP, the majority (43%) were above 61 years followed by 51 to 60 years (34%). In IATP, maximum (35%) were above 61 years followed by 41 to 50 years (23%) in IATP. Between the groups, there was a significant difference in this distribution ($p=0.02$). T2DM is found to be common in this age group.¹²⁶

➤ **Marital status wise distribution**

- In both the groups, majority were married, i.e 94% in STP and 83 % in IATP. Between the group there was a significant difference ($p<0.05$)

➤ **Chronicity of T2DM**

- In STP, there is mean chronicity of 6.6 years and in IATP there is mean chronicity of 5.18 years. Between the group, there is a significant difference ($p<0.05$).

➤ **Dosage of metformin**

- In STP, mean dosage of metformin is 1490 mg and in IATP, mean dosage is 1284 mg. Between the group, there was a significant difference in the dosage of metformin ($p<0.001$).

➤ **Diet adherence (in %)**

- Diet adherence was found more in the IATP compared to the STP ($p=0.001$).

➤ **Exercise /yoga adherence.**

- Exercise/yoga practice adherence were more in IATP compared to the STP ($p=0.001$).

7.2.1. Discussion on Results

- A total of 200 patients were recruited for the study. Twelve patients in IATP and six patients in the STP group discontinued treatment. In the STP group, three subjects dropped out due to relocation, three dropped out because of scheduling conflicts, and one dropped out due to issues complying with the protocol. In IATP group, four migrated to another location, four expressed inconveniences attending the follow-up, and four stated their difficulty complying with the protocol.

- The study showed that study group (IATP) was more effective than control in the management of T2DM. Study group demonstrated efficacy in the primary assessment parameter (HbA1C) and in the secondary assessment parameters, including HOMA IR, serum triglyceride levels, cholesterol, VLDL, FBG, PPBG, anthropometric measures, and DQOL. The serum creatinine, and fasting insulin levels were improved in both groups; however, no appreciable changes were noted in the HDL, LDL, and Hb% levels.

➤ **Discussion on glycemic parameters:**

- The effect of the intervention on HbA1c showed a significant difference ($p<0.001$) in between-group comparison, favoring group IATP.
- The impact of interventions between the group on FBG showed a significant difference ($p=0.02$) with better results in IATP. Within the group, both STP ($p=0.001$) and IATP ($p<0.001$) showed significant results.
- The result of the intervention on PPBG showed that group IATP had significant reduction ($p<0.001$) than STP when compared between the groups

➤ **Discussion on Insulin resistance parameters**

- The result of the intervention on serum insulin revealed a comparable outcome between the group ($p=0.168$). Within the group, both STP ($p=0.001$) and IATP ($p<0.001$) showed significant improvement
- The outcome of the intervention on HOMA IR between the groups showed a significant difference ($p=0.005$) revealing that IATP had greater

improvement. Within the group, both STP ($p=0.001$) and IATP ($p<0.001$) showed significant results.

- Result could be through integrated Ayurveda protocol consists of *Madhumehari ghanavati* (an Ayurveda polyherbal formulation), Ayurveda diet and Yoga.
- **Madhumehari ghanavati**
 - *Meshashringi, Asana, Jambu, Dharuharidra, Tamala patra, Gududchi* are having best *pramehagna property*¹²⁷.
 - *Gymnema sylvestre R. Br., Pterocarpus marsupium Roxb, Syzygium cumini Linn, Berberis aristata DC, Cinnamomum tamala (Buch, Ham), Curcuma longa Linn, Triphala* are having antihyperglycemic and insulin sensitizing action^{128,129,130,131,132,133,134}.
- **Ayurveda diet**
 - Ayurveda food works at insulin resistance characteristics, improved insulin sensitivity. *Tikta* and *Kashaya rasa* food gave beneficial effects in this parameter.
 - Diet helped in balancing *dosha* and *agni*.
 - Improvements in insulin sensitivity were noted, shown by decreased HOMA-IR and HbA1c levels. Patient also reported reduced fatigue and fewer cravings for sweets, indicating enhanced *dhatvagni*.
 - Diet contains time restricted eating pattern. Time restricted eating is a pattern of Intermittent Fasting (IF). A recent meta-analysis reviewed of IF diets found that they reduce insulin resistance¹³⁵.

- Due to the high level of glucose intolerance in the morning we introduced low-carb (LC) breakfasts (using lentils and beans). A randomized trial evaluated the impact of LC breakfast on blood glucose control in T2DM when compared with low fat content breakfast revealed that HbA1c was reduced after 12 weeks of a LC breakfast¹³⁶.
- India's super food, millet, is widely consumed locally and is used in all facets of daily life. Millets are high in fiber, satiating, and minimize meal frequency. An experiment using diabetic mice to test different diets showed that millet can boost insulin sensitivity and lower blood glucose and lipid levels¹³⁷.
- The Ayurveda diet emphasizes more on eating fresh herbal preparations and nuts & seeds. We get the same dietary pattern in mediterranean-style diet. A higher rate of mediterranean diet observance is linked to a 20–23% lower incidence of T2DM¹²⁶ due to its antioxidant and anti-inflammatory properties¹³⁸.

- **Yoga**

- Patient practiced yoga showed lowered serum insulin and Homa-IR indicating better insulin sensitivity.
- There was an observed increase in insulin sensitivity, suggesting that yoga helps the body to use insulin more effectively.
- Participants experienced weight loss or better weight management, contributing to improved metabolic health.

- Yoga practices improved blood circulation and oxygen delivery to cells, supporting overall metabolic processes.
- Yoga might have contributed to reduced systemic inflammation, which is often linked to insulin resistance.
- Yoga, according to various studies, may reduce insulin resistance¹³⁹.
- *Surya Namaskar*, the basic dynamic yoga position that decreases hip circumference and improves glycemic outcomes, is the foundation of physical activity-related yoga¹⁴⁰.
- A review of prior studies on T2DM analysis included nine eligible studies, of which four showed that yoga with the intervention led to a substantial drop in HbA1c compared to the control group¹⁴¹.
- Yoga significantly affects how well T2DM patients use their glucose¹⁴².
- In a study of 35 T2DM patients, yoga intervention significantly improved insulin and HOMA-IR compared to controls¹⁴³.

➤ **Anthropometric outcome**

- Study data indicates that, between the groups, weight reduction was more significant in IATP ($p < 0.001$) than STP. In the BMI parameter also, IATP had significant changes ($p < 0.001$) compared to STP. Within the group, both STP and IATP showed statistical significance in weight and BMI measures ($p < 0.001$). The effect of the intervention on waist circumference between the group showed that IATP group is

better ($p<0.001$) than the STP. Within the group, both STP ($p<0.001$) and IATP ($p<0.001$) showed significant results.

- The results of the intervention on body surface area between the groups showed that group IATP had significant changes ($p=0.005$) than STP. Within the group, both STP ($p=0.01$) and IATP ($p=0.001$) groups showed significant improvement.
- The impact of the intervention on whole body fat % between the groups showed that IATP had a significant outcome ($p<0.001$) than STP. Also, the interventional impact on visceral fat revealed that IATP had a significant outcome ($p<0.001$) than STP. Within the group, both groups showed statistical significance in whole-body fat and visceral fat ($p<0.001$).
- The result of intervention might be due to Ayurveda polyherbal formulation, *Ayurveda* diet and Yoga.

○ ***Madhumehari ghanavati***

- *Vijayasara, Jambu, Triphala, Tamala patra* have *sthoullya and medohara* property¹⁴⁴.
- Based on in vitro and human studies, *Gymnema sylvestre* R. Br¹⁴⁵., *Pterocarpus marsupium* Roxb¹⁴⁶., *Cinnamom Tamala* (Buch,Ham)¹⁴⁷ and *Triphala*¹⁴⁸ showed reduction in weight and BMI.

○ ***Ayurveda diet***

- Low Glycemic index food helped in weight loss.
- *Yava* (barley), *Trina dhanya's* (millets) have *lekhana* action might assisted in *sthoullya* and other related parameters.

- *Mudga* (green gram) has *medohara* property.
- *Shushka phala varga's* (dry fruits) light and digestive, had *kaphahara* action might facilitated in weight loss.

○ **Yoga**

- *Surya Namaskar*, the basic dynamic yoga position that decreases hip and waist circumference and improves glycemic outcomes, is the foundation of physical activity-related yoga¹⁴⁹. It also stimulates agni, enhancing metabolism and aiding in the breakdown of Ama (toxins).

➤ Lipid panel parameters

- In serum triglycerides, when compared between the groups, IATP showed significant changes ($p=0.004$) than STP. Within the group, both STP ($p=0.01$) and IATP ($p<0.001$) had significant effects. HDL and LDL levels were found to be non-significant both between and within the group. Results of intervention on total cholesterol showed that, within the group, IATP showed significant improvement ($p=0.01$), whereas STP showed non-significant changes ($p=0.17$). However, when compared between the groups, there are no significant differences ($p=0.60$). The result of intervention on VLDL showed a non-significant difference between the group ($p=0.57$). Within the group, IATP showed significant results ($p=0.01$), whereas STP showed non-significant improvement ($p=0.08$).

- This result might be due to probable effect of *Madhumehari ghanavati*, Ayurveda diet and Yoga.
- ***Madhumehari ghanavati***
 - *Triphala*, *Haridra*, *Dharuharidra*, *Tamala patra* have *medohara* properties¹²⁷.
 - *Gymnema sylvestre* R. Br¹⁵⁰, *Berberis aristate* DC¹⁵¹, *Triphala*¹⁵², *Cinnamom tamala* (Buch,Ham)¹⁵³ showed lipid lowering potential.
- ***Ayurveda diet***
 - An experiment using diabetic mice to test different diets showed that millet lowers lipid levels¹⁵⁴.
 - Systematic review and meta-analysis reviewed that therapeutic food [herbal preparation] helpful in reducing lipid profile¹⁵⁵.
 - Review of herbal food therapies exerts impact on lipid profile and its related disorders¹⁵⁶.
 - Evidence from clinical trials has shown that plant-based nut-enriched diets are associated with lowering total cholesterol, LDL-C, and TG compared with control diets¹⁵⁷.
 - A randomized controlled trial revealed that regular legumes and lentils consumption had a cholesterol lowering effects¹⁵⁸.
 - Millets have *kapha* and *medohara* actions
 - *Triphala*, *haridra*, *dharuharidra* have *lekhana* action might helped in *sthoulya paramaeters*.

○ **Yoga**

- Yoga practitioners reported considerably lower triglyceride levels compared to those who exercised regularly¹⁵⁹.
- Previous trial, after intervention with yoga for a period of 3 months the study group showed a decrease in total cholesterol, triglycerides, and LDL, with an improvement in HDL compared to oral hypoglycemic agents (OHA) group¹⁶⁰.

➤ **Safety profile**

- Effect of therapy on serum creatinine showed comparable outcome between the group ($p=0.11$). Within the group, both STP and IATP showed significant changes ($p<0.001$).
- Both interventions had favorable safety profiles. Serum creatinine levels remained within the normative ranges both before and after interventions. Adverse events were mild and subsided without any additional intervention.

➤ **Quality of life**

- The effect of intervention on satisfaction score showed a significant difference ($p=0.0001$) favoring IATP. Within the group analysis of parameter on satisfaction score revealed that both the groups had shown significance. The improvement in IATP was at all-time points of 30th, 60th and 90th day of intervention ($p=0.0001$). In the STP, improvement was seen on the 60th and 90th day of intervention ($p=0.0001$). The effect of intervention on impact score showed a significant difference ($p=0.0001$) favoring

IATP. The analysis of parameter impact score revealed that both the groups had shown significance. The improvement in IATP was at all-time points of 30th, 60th and 90th day of intervention ($p=0.0001$). In IATP, improvement was seen on the 60th and 90th day of intervention ($p=0.0001$). The concern domain (related to social/vocational) showed comparable results between the groups. In concern (social/vocational) domine, within the group result revealed that IATP improved at all-time points ($p=0.001$). In IATP, improvement was not significant. The overall score demonstrated that there is a large difference between the groups ($p=0.0001$) with better improvement in the IATP group ($p<0.001$).

- Result of intervention due to Ayurveda polyherbal formulation (*Madhumehari ghanavati*), *Ayurveda* diet and *Yoga*.

- ***Madhumehari gana vati***

- Antihyperglycemic and insulin sensitizer effect of the drugs without any major adverse events
- Aids in healthy weight loss
- Hence found results in quality of life

- ***Ayurveda* diet**

- Balancing glycemic outcome.
- Supported in digestive health.
- Provides good weight management.
- Fulfilled nutritional requirement [better performance].

- *Yoga*
 - Yoga seeks to achieve a state of physical, emotional, and spiritual well-being by balancing the body, mind, and emotions.
 - Yoga has a positive effect on improving sleep quality.
 - Hence proved better quality of life
 - Dosha Balance: Regular yoga practice harmonizes Vata, Pitta, and Kapha, aiding in overall metabolic stability.
 - Asanas such as Surya Namaskar and Pranayama (breath control) stimulate Agni, reduce stress, and regulate hormonal functions.
 - Sleep quality: Practices like Shavasana and meditation reduce Vata disturbances, promoting better sleep quality and emotional resilience.
 - Improved quality of Life: The integrative approach of yoga supports physical flexibility, emotional calmness, and mental clarity, enhancing satisfaction and impact scores across interventions.
 - In summary, the combined effect of Madhumehari Ghanavati, Ayurveda diet, and yoga integrates the principles of Tridosha balance, improved Agni, and Ama elimination, thereby supporting glycemic outcomes, weight management, and a holistic improvement in quality of life.

➤ ***Prameha* parameters**

- Effect of intervention on *prameha poorvaroopa* outcome showed significant difference favoring IATP in *angashaitilya*, *alasya*, *shitapriyatva*, *angaganda*, *swedadikya* and *angasada* features. Impact of intervention on *Prameha roopa* parameter showed significant difference towards IATP in *mutramadhurya*, *prabhutamutrata*, *pipasa*, *Khsudadikyata*, *klama* and *Purishabaddata*.
- Drugs such as *Jambu*, *Asana*, *Haridra* are having potent anti-diabetic activity, also they are having *pitta* mitigating property, hence might helped in symptoms of *Pipasadikyata*, *kshudadikyata* etc. An open label clinical trial conducted in 4 centres of India to see the efficacy of *vijayasara* (*Pterocarpus marsupium Roxb*) in non-insulin dependent diabetes mellitus had shown reduction in glycaemic parameters and lipid changes¹⁶¹. The research done on the extract from *Syzygium cumini* demonstrates the existence of phenolic compounds with antioxidant and anti-glycation properties that can mediate their anti-diabetic benefits¹⁶². A meta-analysis of various studies has shown the beneficial effects of curcumin and its preparation in Asian pre-diabetes and T2DM patients by reducing HbA1c¹⁶³. *Meshashringi*, *Tamala patra*, *Daruharidra* have *kapha medohara* and *lekhana* (scrapping) action might help in reversing the pathogenesis^{164,165}. A clinical trial on T2DM, administered with 500 mg of *Meshashringi* (*Gymnema sylvestre* R. Br.) along with diet for a period of 90 days shown beneficial effect in polyphagia

and other symptoms¹⁶⁶. Patients with T2DM who received 1 mg of *daruharidra* fruit extract showed results in blood glucose regulation¹⁶⁷. *Guduchi* and *Triphala* have added *rasayana* advantages^{168,169} in addition to the ones, which may have an impact on *Angashitilya*, *Sada*, and *Klama*.

- The *Ayurvedic* concept of dietary recommendations for lifestyle diseases is *guru cha aatarpana*, i.e., food that is heavy and rich in nutrients without causing over nourishment¹⁷⁰ and avoids excess fat storage, like foods made of millet. This theory helps to balance metabolism and prevent overeating, which is why this study found effective outcomes. This diet contained most of the plant-based food. A meta-analysis of six randomized controlled trials (N = 255) found that plant diets were associated with a 0.4% larger drop in glycated hemoglobin (HbA1c) than other suggested dietary patterns for diabetic people¹⁷¹. Review on benefits of *yogasana*'s reveal that, ten minutes of yoga intervention combined with standard medical care for 10 minutes helped to improve metabolic health significantly. Combined effect of *Madhumehari ghanavati* with *pathyahara* and integration of *yoga* showed benefits in symptomatology of *Prameha*.

- ***Samprapti vighatana chikitsa in Prameha: Therapeutic role of madhumeharighanavati***

- *Madhumeharighanavati* pacifies the *kleda*, *Bahudrava kapha*, *abaddha medas* as most of the ingredients are *Tikta-Katu-Kashaya* rasa having *kleda-medo upashoshana* properties and *Laghu-Ruksha* in *gunas*.

- It also pacifies *medovaha srotodushti lakshanas* by their *laghu*, *ruksha*, and *teekshna guna*, *medohara* and *deepana-pachana* properties.
 - This can prevent the *medo dushti* that would lead to *chirakalina avastha* of *madhumeha*.
 - Simultaneously reduction of *asthiratva* (*bahudrava kapha*, *Kleda*, *abaddha medas*) of dosha and *dhatu* leading to *bala vriddhi*.
- **Mechanism of Action of Madhumehari ghanavati According to Ayurvedic Principles**
- *Madhumehari ghanavati* acts on multiple Ayurvedic principles to manage *Prameha* and its associated complications. It balances *Kapha* and *Pitta* doshas, which are primarily vitiated in *Prameha*. It also helps regulate *Vata dosha*, which becomes deranged in chronic stages, leading to complications.
 - Majority of ingredients have *pramheagna* potential.
 - Key herbs like *Meshashringi* acts as *pramehagna*. *Vijaysar* (*Pterocarpus marsupium*) has *rasayana* and *balya* effects helps in *dhatukshaya*.
 - The formulation's *Medohara* (anti-obesity) action is achieved through ingredients like *Haritaki*, *Bibhitaki*, and *Amalaki*. These herbs pacify *meda dhatu dushti* (derangement of fat metabolism), a key pathological factor in *prameha*.
 - Herbs like *Jambu* (*Syzygium cumini*) and *Daruharidra* (*Berberis aristata*) act as *Raktashodhaka* (blood purifiers), detoxifying the blood and controlling excessive glucose levels. *Methika* (*Trigonella foenum-graecum*) slows carbohydrate absorption and strengthens *Agni* (digestive

fire), improving digestion and metabolism at the cellular level, which aligns with correcting *Ama* (toxic byproducts) formation, a critical aspect in *Prameha* pathogenesis.

- Additionally, *triphala* and *haridra* provide *lekhana* (scraping) and *shothahara* actions, reducing inflammatory mediators and preventing diabetes-related complications. *Twak* supports glucose utilization and enhances cellular function, ensuring balanced *dhatvagni* (metabolic fire at the tissue level).
- **Mode of action of Ayurveda diet**
 - Ayurveda diet primarily focusses on *kapha* and *pitta dosha*, strengthen *agni* (digestive fire), and regulate *Meda dhatu* (fat tissue).
 - *Laghu*, *Ruksha* (dry), and *tikta-kashaya rasa pradhana* which counteract the *snigdha* (unctuous) and *guru* (heavy) qualities of *Kapha*, aid in glucose regulation and enhance *shodhana* of *rasa* and *rakta dhatu*. Grains like *yava* and millets are *Medohara* (anti-obesity) and help maintain stable blood sugar levels while improving tissue metabolism. Foods like *mudga* (green gram) and spices such as *haridra*, *methika*, *twak* are included to enhance *agni*, reduce *ama* (toxins), and improve glucose metabolism at the cellular level. Ayurvedic principles recommend *Ahara vidhi* (dietary rules) like eating warm, freshly prepared meals in moderation to prevent *agni mandya* (weakened digestive fire) and regulate blood sugar. *Langhana* is also suggested to reduce *Ama* and support fat metabolism, promoting *srotoshuddhi* (cleansing of channels). Incorporating *desha* (geographical consideration) and *Ritu* (seasonal) considerations into dietary planning ensures alignment with the

body's natural rhythms, aiding metabolic harmony. Foods with *Vata* balancing properties are included in advanced stages of *prameha* to prevent complications. Overall, the *Ayurvedic* diet not only focuses on managing blood sugar but also aims to restore metabolic balance, detoxify the body, prevent complications, and promote holistic well-being by aligning with the fundamental principles of *ahara*, *agni*, and *dosha samya* (*dosha* balance).

- **Mode of action of Yoga**

- *Asanas* improving its functional capacity and aiding insulin secretion. These postures also enhance circulation, improve digestion, and activate *Agni* (digestive fire), reducing *Ama* (toxins).
- *Pranayama* improve oxygenation, pacify the mind, and reduce *Kapha* and *Pitta* aggravations, addressing the root cause of *Prameha*. *Pranayama* helps balance the autonomic nervous system, reducing stress-induced hyperglycemia.
- Meditation and mindfulness: Practices like *dhyana* (Meditation) and *Yoga nidra* (Yogic Sleep) aid in managing mental stress, which is a significant contributing factor in *Vata prakopa* and subsequent complications of *Madhumeha*.
- *Yoga* promotes the reduction of *medo dhatu dushti* (fat tissue imbalance) and improving metabolic activity, reducing insulin resistance.

- **Safety profile**

- Both the group showed favorable safety outcomes

- Both the group exhibited no major adverse events throughout the study
 - This integrated protocol showed additive effect, underscores the potential for these modalities to be integrated into conventional diabetes management strategies.
-
- The study was a well-designed randomized controlled trial.
 - This is one of the first study to use Homa IR as an assessment tool in uncontrolled T2DM.
 - The assessment of the Ayurveda treatment protocol aligns with principles and practices of Ayurveda. The study's utilization of an add-on approach alongside standard care for T2DM patients enhances its external validity, reflecting the widespread acceptance of Ayurveda in comprehensive healthcare settings.
 - The multimodal treatment exhibited an augmentary effect, enhancing outcomes through synergistic interactions rather than antagonistic ones.

8. SUMMARY

The dissertation entitled “Efficacy of Integrated Ayurveda treatment protocol in uncontrolled T2DM mellitus-A Randomized controlled clinical trial” comprises of following:

Introduction: It comprised of description of Diabetes, its global burden, knowledge of T2DM mellitus and *prameha*, epidemiology of T2DM, risk factors for T2DM, its etiopathogenesis, present treatment modalities with their adverse events. Further the need of planning integrated Ayurveda protocol which comprised Ayurveda polyherbal formulation (*Madhumehari ghanavati*), Ayurveda diet and yoga for the management of T2DM is explained.

Objective: The objective is to evaluate the efficacy of Integrated Ayurveda treatment protocol as add-on therapy in patients of uncontrolled T2DM in achieving the glycemic control assessed through HbA1C and to compare the effect of Integrated Ayurveda treatment protocol and Standard treatment regimen intervention on changes in biochemical parameters of T2DM (Fasting Insulin, HOMA IR, Lipid profile) and quality of life.

Review of Literature: Under review of literature, disease review and drug review are explained. In disease review understanding of T2DM, its risk factors, etiopathogenesis, diagnostic criteria, management options were explained. The Ayurvedic perspective of T2DM in terms of *prameha*, its *nidana*, *samprapti*, *samprapti ghataka* are further elaborated. *Chikitsa* is explained as *nidana parivarjana*, *shodhana*, *shamana*, *rasayana* and *pathyapathya* in detail. In drug review, *rasapanchaka* of ingredients of *madhumehari ghanavati* described along with their

active chemical constituent. Modern management of T2DM, benefits and adverse events were explained.

Materials and Methods: Methodology is described under 3 headings: Pharmaceutical study, Analytical study, Clinical study. In Pharmaceutical study, identification, and authentication of raw drugs of *madhumehari ghanavati*, its preparation method was explained. In the analytical study part, an analytical report of finished products was described. Under the clinical study part, data collection methods, inclusion criteria, exclusion criteria, subjective and objective assessment parameters, intervention details, CONSORT chart were explained.

Observation: Demographic variables such as Age, gender, religion, education, occupation, socioeconomic status, marital status, chronicity of T2DM, medication duration & dosage, family history of T2DM, personal history, habits, appetite, sleep, physical activity, mental health, *prakrati*, *saara* variables were compared between the two groups.

Results: The outcome of parameters like HbA1C, FBS, PPBS, insulin, Homa IR, weight, BMI, Waist Hip ratio, Body surface area, Body fat(%), visceral fat(%) were explained.

Discussion: Under this discussion, observation and results were mentioned with reasons and critically appraised the results.

Conclusion: Integrated *Ayurveda* treatment protocol proved effective in the management of Uncontrolled T2DM mellitus.

9. CONCLUSION

- The Integrated Ayurveda Treatment Protocol (study intervention) in uncontrolled T2DM showed significant efficacy in the primary outcome criteria (HbA1c).
- Study intervention showed better efficacy in other glycaemic parameters (FBG, PPBG).
- Study intervention exhibited improved insulin resistance parameters (Serum insulin and HOMA IR).
- Study intervention led to enhanced quality of life in Uncontrolled T2DM.
- Both the groups experienced mild and small adverse drug reactions (ADR's), with normal creatinine levels indicating safety.
- Study intervention had fewer ADRs, better adherence, and demonstrated an augmentary effect.
- The multimodal treatment approach combining Ayurveda and conventional therapy showed good safety, compliance, and efficacy.
- Integrating Ayurveda treatment alongside conventional therapy could be a beneficial approach for improving glycemic control and overall management of Type 2 DM, potentially leading to better patient outcomes and quality of life.

10. LIMITATION OF STUDY

- Self-reported adherence to diet, yoga, nutrition, and exercise.
- It is challenging to determine the specific effects of individual components within multi-modal interventions.
- While the Integrated treatment protocol incorporating *Ayurveda* diet and yoga demonstrates efficacy among those who adhere to and believe in its principles, however its feasibility and acceptability in non-Indian settings and cultures require investigation.

11. RECOMMENDATIONS FOR FURTHER STUDY

- Long term interventional studies
- Oral glucose tolerance tests can be performed to check diabetic remission.
- Trial intervention consisting of conventional medications, Ayurvedic drugs, Ayurveda diet, and yoga, there's a need to study drug-to-drug and drug-to-food interactions in multimodal treatments.
- Additionally, exploring Integrated Ayurveda protocol application in special diabetic groups like gestational diabetes presents an avenue for further research and potential refinement of treatment strategies.
- Further studies should aim to establish a validated diagnostic framework for T2DM based on Ayurvedic principles, ensuring reliability and reproducibility across diverse patient populations.

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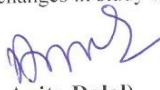
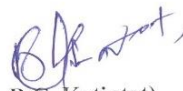
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ANNEXURE 1: ETHICAL CLEARANCE AND CTRI REGISTRATION

	KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (Formerly known as KLE University) (Deemed-to-be-University established u/s 3 of the UGC Act, 1956) Accredited 'A' Grade by NAAC (2 nd Cycle) Placed in Category 'A' by MHRD (GoI) JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India ☎: 0831-2444444 FAX: 0831-2493777 Web: http://www.kledeemeduniversity.edu.in E-mail: info@kledeemeduniversity.edu.in	
	Ref.No.KAHER/EC/20-21/001/11	4 th September 2020
To, Dr. Suketha Kumari Part-Time Ph.D. Research Scholar, 2019-20 Batch, Faculty of Ayurveda, KAHER, Belagavi.		
Dear Research Scholar,		
The KAHER Ethics Committee on Human Subjects for Ph.D. Research Project met on Thursday, the 20th February, 2020 to consider your application for approval of the research project "Efficacy Of Integrated Ayurveda Treatment Protocol In Uncontrolled Type 2 Diabetes Mellitus: A Randomised Controlled Clinical Trial."		
As there are no ethical issues involved in your proposed research project, the committee has provided approval for this research project.		
You are requested to report to Ethical Committee of the following:		
1. Any deviation from or change of the protocol. 2. Any changes in study documents.		
 (Dr. Anita Dalal) Member-Secretary Ethical Committee (Human) for Ph. D. Research KAHER, Belagavi.	 (Dr. B.C. Kotintot) Chairman Ethical Committee (Human) for Ph. D. Research KAHER, Belagavi.	
CC to: - The Director Research Foundation, KAHER, Belagavi. - The Director Academic Affairs, KAHER, Belagavi. - The Registrar, KAHER, Belagavi. - Special Officer to Hon. Vice Chancellor, KAHER, Belagavi.		



Institutional Ethics Committee for Research on Human Subjects
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMK/21/PhD/SK

Protocol Title: Efficacy of Integrated Ayurveda Treatment protocol in Uncontrolled Type 2 Diabetes Mellitus: A Randomised Controlled Clinical Trial

Principal Investigators/Co-investigators: Dr Suketha Kumari

Name & Address of Institution:

KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya & KLE Ayurved Hospital,
Shahapur, Belagavi

New Review ☒

Revised Review ☐

Expedited Review ☐

Date of Review (DD/MM/YY): 04/09/2021

Date of previous review, if revised application:

Name of the Reviewers who attended the meeting:

Dr. Supriya Bhalerao, Dr. Harsha Hegde, Dr. Rajashree Kamat, Dr. Pradeep Shinde, Mr. Sudheer Kulkarni, Mrs. Arati S. Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R. Tubaki, Dr. Giridhar Vedantam, Dr. Aziz Arbar

Decision of the the Ethics Committee:

Recommended

☒

Recommended with suggestions

☐

Revision

☐

Rejected

☐

Suggestions/ Clarifications / Reasons/ Remarks:

- NIL

Recommended for a period of : Two Year

Please note *

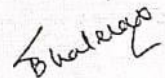
- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse



Dr. Basavaraj R Tubaki
(Member Secretary)

Member Secretary
Institutional Research Committee
CLINICAL

KAHL'S SHAI BIRK & SONS Private Limited
Bengaluru, Karnataka, India



Dr. Supriya Bhalerao
(Chairperson)

CTRI Number	CTRI/2020/12/029762.	
Last Modified On	11/12/2020	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Drug Ayurveda Yoga & Naturopathy Screening	
Study Design	Randomized, Parallel Group, Active Controlled Trial	
Public Title of Study	Ayurveda and Yoga treatment for Diabetes	
Scientific Title of Study	Efficacy of Integrated Ayurveda Treatment Protocol in Uncontrolled Type 2 Diabetes Mellitus : A Randomised Controlled Clinical Trial	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Suketha Kumari
	Designation	Phd Scholar
	Affiliation	KAHERs Shri B M Kankanawadi Ayurveda Mahavidyalaya Shahapur Belagavi Karnataka
	Address	OPD No.3, Dept of Kayachikitsa KLE Ayurveda Hospital and Research centre Belagavi Karnataka Kayachikita dept, KLE Shri B M Kankanawadi Ayurveda Mahavidyalaya, Belagavi Belgaum KARNATAKA 590003 India
	Phone	9483637757
	Fax	
	Email	sukethashetty411@gmail.com
Details Contact Person /Scientific	Details Contact Person (Scientific Query)	

ANNEXURE 2: STUDY DRUG ANALYSIS

SHRI B M KANKANAWADI AYURVED MAHAVIDYALAYA	
A Constituent Unit of KLE ACADEMY OF HIGHER EDUCATION & RESEARCH (DEEMED-TO-BE-UNIVERSITY)	
(Re-Accredited 'A' Grade by NAAC (2nd Cycle) Placed under Category 'A' by MHRD GoI)	
CENTRAL RESEARCH FACILITY	
(AYUSH Approved ASU Drug Testing Laboratory Lic. No.TL-8/2011)	
Outward No:-BMK/CRF/319/2021-22	
Reference No:CRF/FG/196/2021-22	Registration Dt:-03/07/2021
Submitted by:KLE Ayurved Pharmacy	Requisition No:KLE/AP/01/2021-22
Sample : Madhumehari Gana Vati	Batch No. : I
Ref : Pro	Sample Qty: 40 Tab
(* N/A - Not Available)	Mfg Date: July-2021
	Part/Form: Vati
	Report Date : 27/07/2021
	Exp Date : June 2024
TEST REPORT	
Form-50 [See Rule 160-D (f)]	
(The Drugs & Cosmetic Act 1940 and the rules there under)	
Description Macroscopic :	
TESTS	RESULTS
FORM	: Vati
COLOUR	: Blackish
ODOUR	: Characteristic
Physico Chemical Standards :	
TESTS	RESULTS
Loss on drying	:1.796 %
Total Ash	: 9.643 %
Acid Insoluble Ash	: 2.077%
Water soluble extractive	:64.495 %
Alcohol soluble extractive	:16.265 %
Average Weight	: 0.487 gm
Hardness(Vertical)	: 4kg/cm
Disintegration time	: 21 Minutes
Note : API Standards are not Available.Given results are of the submitted sample.	
ANALYST	AUTHORISED SIGNATORY

SHRI B M KANKANAWADI AYURVED MAHAVIDYALAYA
 A Constituent Unit of KLE ACADEMY OF HIGHER EDUCATION & RESEARCH (DEEMED-TO-BE-UNIVERSITY)
 (Re-Accredited 'A' Grade by NAAC (2nd Cycle) II Placed under Category 'A' by MHRD Govt)

CENTRAL RESEARCH FACILITY

(AYUSH Approved ASU Drug Testing Laboratory Lic. No.TL-8/2011)

Outward No:-BMK/CRF/ /2021-22

Reference No:CRF/FG/196/2021-22

Submitted by:KLE Ayurved Pharmacy

Sample : Madhumeha ghan Vati

Ref : Prop

(* N/A - Not Available)

Batch No. : I

Sample Qty: 40Tab

Mfg Date:July 2021

Registration Dt:-03/07/2021

Requisition No:KLE/AP/01/2021-22

Part/Form: Vati

Report Date: 17/07/2021

Exp. Date : June 2024

TEST REPORT

Form-50 [See Rule 160-D (f)]

(The Drugs & Cosmetic Act 1940 and the rules there under)

Test for specified Micro -Organisms (Qualitative)

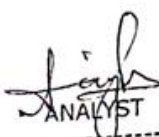
	LIMITS (As per IP)	RESULTS
E coli	Absent/100ml	Absent
S aureus	Absent/100ml	Absent
P aeruginosa	Absent/100ml	Absent
S abony	Absent/100ml	Absent

Microbial limit test (Quantitative)

	LIMITS (As per IP)	RESULTS
Total Bacterial Count	30 - 300 cfu/ml	: 07cfu/ml
Total Fungal Count	10 - 100 cfu/ml	: 03cfu/ml

(Standards referred above are as per IP/In house Specification)

*** In my opinion the Sample is standard quality**


ANALYST


AUTHORISED SIGNATORY

ANNEXURE 3: CASE REPORT FORM

**STUDY TITLE: “EFFICACY OF INTEGRATED AYURVEDA TREATMENT
PROTOCOL IN UNCONTROLLED T2DM MELLITUS – A RANDOMISED
CONTROLLED CLINICAL TRIAL”**

CASE RECORD FORM

Patient Identifier No. (MR.NO):	Initials of the Patient:
Subject number:	Study group:

PRINCIPAL INVESTIGATOR

Dr. Suketha Kumari

Ph.D Scholar

Dept. of Kayachikitsa

KAHER'S Shri B.M.K Ayurveda Mahavidyalaya

Post-Graduation Studies & Research Centre

Shahapur, Belagavi-Karnataka.590003

UNDER THE GUIDANCE OF

Dr. B.R.Tubaki MD, Ph.D. VSF

Professor and Head, Dept of Kayachikitsa

KAHER's Shri BMK Ayurveda Mahavidyalaya,

Shahapur, Belagavi, Karnataka, 590003

CO-GUIDANCE

Dr. Rekha Patil

Professor, Dept. Of Medicine

KAHER's JN Medical College, Belagavi, Karnataka, 590003

GENERAL INSTRUCTION

This document is a case report from for a human research study. The study is planned to be in compliance with the Indian schedule Y of D & C Act of 1940 and the ICH-GCP as also the ICMR guidelines. An Institutional Ethics Committee (IEC) approval

is already obtained for this study. Please go through all the points in the CRF and clarify the doubts. It is very much important that the data filled in the CRF must be unbiased and the identity of the trial subject is well protected

INDEX

Sr.no	Title	Page. No
1.	Patient information sheet	03
2.	Informed consent form	07
3.	Eligibility Form	09
4.	Subject enrollment form	10
5.	Medical History of Patient	11
6.	Assessment Parameters	16
7.	Adverse Event	21
11.	Medicine Diary	23
12.	Summary	26
13.	Prameha –Mutra Pariksha (Annexure- I)	27
14.	Prameha Laxana chart(Annexure-II)	28

PATIENT INFORMATION SHEET

STUDY TITLE

“EFFICACY OF INTEGRATED AYURVEDA TREATMENT PROTOCOL IN UNCONTROLLED T2DM MELLITUS– A RANDOMISED CONTROLLED CLINICAL TRIAL”

STUDY SITE: KLE Ayurveda hospital and Medical Research Centre, Shahapur, Belagavi-Karnataka

STUDY TYPE: Randomized Controlled Clinical Study

PURPOSE OF THE RESEARCH STUDY: You are being invited to participate in a research study of Ayurveda Treatment Protocol in Uncontrolled T2DM Mellitus. Objective of this study is to evaluate the efficacy of Integrated Ayurveda treatment protocol as add-on therapy in patients of uncontrolled T2DM in achieving the glycaemic control assessed through HbA1C, also to compare the efficacy of Integrated Ayurveda treatment protocol and Standard treatment regimen intervention on changes in biochemical parameters of T2DM (Fasting Insulin, HOMA IR, Lipid profile) and quality of life. You were selected as a possible subject in this study because you fulfil the inclusion criteria. The study drugs are being practiced since ancient times and are mentioned in Ayurveda classics for the treatment of T2DM mellitus. We hope that your participation will help us to generate data on its efficacy in the management of T2DM mellitus.

Although this Ayurveda treatment protocol is a part of standard medical care, in this study these procedures are being performed for the purpose of the research.

This study will recruit 200 subjects over a period of 24 months.

When your participation in the study ends, you will no longer have access to study medications unless special additional arrangements are made by the Principal Investigator

STUDY DETAILS AND VISIT SCHEDULE:

GROUP	INTERVENTION
STP	Standard anti diabetic care Tab.Metformin($\geq 1000\text{mg/day}$) + Add on anti-diabetic medication + Nutritional and lifestyle management advice
IATP	Tab. Metformin ($\geq 1000\text{mg/day}$) + Madhumeha Ghanavati 500 mg 2 tabs thrice daily after meals with water + Ayurveda diet +Yoga

If you agree to take part in this study, you will be asked to take standard antidiabetic treatment or Ayurveda treatment protocol with diet and yoga for the duration of 90 days (According to the schedule of the Group to which you are randomized) and as per the doses decided by the investigator for a period of 90 days.

Your participation in the study will last for 90 days. You will need to visit the doctor for 4 times during the study. You will be assessed for changes in BMI, waist circumference, blood parameters related to diabetes. You will also be assessed for diabetes quality of life.

Schedule of visit & procedure:

Visit 1: The day of enrolment

Visit 2: 30th day after intervention

Visit3: 60th day

Final visit: 90th day

Investigation: Hb%, FBS, PPBS, Urine Sugar, HbA1C, Fasting insulin, Lipid profile and serum creatinine will be done before and after the intervention.

YOUR RIGHTS AS A SUBJECT

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you or your legal representative will be informed in a timely manner by the Principal Investigator or his/her representative.

By signing and participating in the trial, you do not waive any of your legal rights to revoke your consent and withdraw from the trial at any time.

YOUR RESPONSIBILITY IN THIS STUDY

If you agree to participate in this study, you should

- Take the study drug as instructed and follow the advice given to you by the study team.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.
- Be prepared to visit the hospital and undergo all the procedures that are outlined above.

CONFIDENTIALITY

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your investigator(s) will have access to the confidential information being collected.

However, regulatory agencies, institution ethics committee will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the informed consent form attached, you or your legal representative is authorizing such access to your study and medical records.

Data collected and entered the case report forms are the property of the institution. In the event of any publication regarding this study, your identity will remain confidential.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

Your doctor, the Principal Investigator may stop your participation in the study at any time for one or more of the following reasons.

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- If you experience Adverse Events/Serious Adverse Events.
- The Principal Investigator decides that continuing your participation could be harmful.
- Subject need treatment not allowed in the study.
- Other administrative reasons.

BENEFITS AND RISKS

If you participate in this trial, you may reasonably expect to benefit from consuming the medicines may cure your disease. Your participation is helpful to provide a better service to the patients in future. There is no known risk involved in this study.

FINANCIAL CONSIDERATIONS:

If you take part in this study, the medicine Madhumeha Ghanavati, dietary & Yoga advice and all investigations carried out will be free of cost.

RESEARCH RELATED INJURY AND COMPENSATION

The hospital does not make any provisions to compensate trial subjects for research related injury. However, you will be provided medical care at this institute for any physical injury or illness that occurs as a direct result of your participation in this study. This medical care will be at no cost to you. By signing this consent form, you will not waive any of your legal rights.

WHO TO CONTACT IF YOU HAVE QUESTIONS

In case you have any doubts regarding your rights as a research participant or you feel that the study has violated your rights as a subject you may contact:

Dr.Suketha Kumari- sukethak.kaher@kleayurworld.edu.in Ph:9483637757

Dr.B.R.Tubaki- basavarajtubaki.kaher@kleayurworld.edu.in Ph:9448634660.

Hospital Contact Number – **0831-2486286**

IN CASE OF DOUBTS OR COMPLAINTS

In case you have any doubts regarding your rights as a research participant or you feel that the study has violated your rights as a subject you may contact **Dr. B.R.Tubaki, (Ph:9448634660)** member secretary of the KLE Ayurveda Hospital Ethics Committee.

INFORMED CONSENT FORM

I confirm that I Mr. _____ have read and understood the information sheet - for the above research study and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. I understand that the Investigator or others working in their behalf will not need my permission to look at my health records. I agree to this access. However I understand that my identity will not be revealed in any information released to the third parties or published. I agree not to restrict the use of my data or results that arise from this study.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTOOD THE ABOVE INFORMATION. YOU HAVE DISCUSSED THIS PROJECT WITH THE PERSON OBTAINING CONSENT AND YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Signature of Participant/ Date Signature of Person obtaining the Consent / Date

Name & Address of Participant Name of Person obtaining the consent/

Designation_____

Signature of Witness/ Date_____

Name and Address of Witness & Relationship to Participant:

SUBJECT ENROLMENT FORM

PROTOCOL NUMBER	SUBJECT NUMBER
SUBJECT INITIALS	VISIT DATE

NAME:

AGE: _____ YRS.

SEX: M/F

RELIGION:

O.P.D NO:

EDUCATIONAL STATUS:

I.P.D.NO:

OCCUPATION:

D.O.A:

SOCIAL STATUS:

D.O.D:

MARITAL STATUS: UM/M/D/W

DESHA:

ADDRESS:

CONTACT NO:

EMAIL ID:

DATE INFORMED CONSENT SIGNED:

ELIGIBILITY FORM**Diagnostic Criteria:****Yes / No**

HbA1c of more than or equal to 7 -10.5%

☐ ☐**Inclusion Criteria****Yes / No**☐ ☐

1. Diagnosed T2DM with age IATPetween 18 to 70 years

☐ ☐

2. Insufficient blood glycaemic control for a period of 90 days

before screening while on stable treatment with metformin (≥ 10 g ☐ ☐ ☐

3. Glycosylated hemoglobin (HbA1c) between 7% -10.5%

4. Subject who submit a written informed consent

Exclusion Criteria**Yes / No**6. Uncontrolled hypertension (with BP $\geq 140/90$ mmHg)☐ ☐

7. Established diagnosis of CAD or any other clinically

☐ ☐

significant cardiovascular disease

8. Established cases of cerebro-vascular accidents such as stroke etc.

☐ ☐

9. Any diabetic complications

(Diabetic Neuropathy, Retinopathy, nephropathy, wounds or ulcers.) ☐ ☐

10. Pregnant and lactating women

- Does the patient satisfy Eligibility Criteria:

Yes /No

- Does the patient consent to participate in the study: Yes /No
- Have you enrolled the subject, despite the subject not satisfying all inclusion / exclusion criteria- Yes/No
- If YES, please specify reason for enrolling:
- **Subject:** Enrolled / Excluded
- If excluded reason for exclusion:

SUBJECT ENROLMENT FORMAge: (IN YEARS)

Sex: MALE () FEMALE () (Put ✓ in appropriate option)

MR Number: Subject Number: Subject Initials: Date informed consent signed: Date subject started the study: **MEDICAL HISTORY OF PATIENT**

Chief Complaints:	Yes/No	Duration

• Frequent urination		
• Dryness of palate		
• Excessive Sweating		
• Fatigue		

ANUBANDHI VEDANA (Associated Complaints):	Duration

VEDANA VRITTANTA (History of present Illness):

History of Past Illness:**Duration****Diseases:** Hypertension, Tuberculosis, Bronchial Asthma, Dyslipidemia

Known Case of Diabetes since month/years

Childhood diseases:

Any Congenital Abnormality:

Surgery:

Other:**Treatment History:**

Medicines for diabetes:

Any other: _____

Medicines:

Sl. No.	Medicine	Dose	Duration	Reason for taking

Family History:

H/O DM in Family: Yes / No

If Yes, Mention the affected: _____

H/O Metabolic Syndrome in family members: Yes / No

Personal History:

Personal History	Particulars		
Bowel Frequency: Consistency: Contents	Regular	Irregular	-
Micturition	Frequency	-	-
Sleep	Normal Day Night	Disturbed Day Night	Increased
Appetite	Normal	Decreased	Increased
Diet	Vegetarian	Mixed	-
Intake of Water in litres/day			
Mental Stress	Not much	Moderate	Severe
Emotional Status	Calm/Anger	Anxiety/Tension	Depression/Irritation

Gynaecological & Obstetric History: Applicable (1)

Not Applicable (2)

If applicable, then a) Age of menarche _____ years.

b) Age of menopause: _____ years.

c) LMP _____

Habits:

Sl. No.	Habits	Quantity / day	Duration	At present
1	Smoking			

2	Tobacco			
3	Alcohol			
4	Drug Addiction			
5	Tea			
6	Coffee			
7	Others			

General Examination:

	0th Day	30th day	60th Day	60th Day
Built				
Pallor				
Icterus				
Cyanosis				
Clubbing				
Lymphadenopathy				
Oedema				

Vitals	0 th Day	30 th day	60 th Day	90 th Day
Blood Pressure				
Pulse				
Respiratory rate				
Temperature				

Systemic examination:

- CNS_____
- CVS_____
- RS_____
- Abdominal Examination_____

ASHTASTHANA PARIKSHA:

Parikshya	0 th Day	30 th Day	60 th Day	90 th Day
Nadi				
Mala				
Mutra				
Jiwha				
Shabda				

Sparsa				
Drika				
Akruti				

DASHAVIDHA PARIKSHA:

Prakruti: V (1) P (2) K (3) VP (4) VK (5)

PK(6) S (7)

Vikruti:

Sara:

Samhanana: Avara (1) ☐ Madhyama (2) ☐ Pravara (3) ☐

Pramana: Avara (1) ☐ Madhyama (2) ☐ Pravara (3) ☐

Satmya: Avara (1) ☐ Madhyama (2) ☐ Pravara (3) ☐

Satva: Avara (1) ☐ Madhyama (2) ☐ Pravara (3) ☐

Aharashakti: Abhyavarana Shakti: Avara (1) ☐ Madhyama (2) ☐ Pravara (3) ☐

Jarana Shakti: Avara (1) ☐ Madhyama (2) ☐ Pravara (3) ☐

Vyayama Shakti: Avara (1) ☐ Madhyama (2) ☐ Pravara (3) ☐

Vaya: Yuva (1) ☐ Madhyama (2) ☐ Vriddha ☐

Assessment Parameters

Anthropometric measurements:

Particulars	0 th day	90 th day
Weight		

Height		
BMI		
Mid Arm Circumference	Rt-	Rt-
	Lt-	Lt-
Mid-thigh circumference	Rt-	Rt-
	Lt-	Lt-
Biceps	Rt-	Rt-
	Lt-	Lt-
Triceps	Rt-	Rt-
	Lt-	Lt-
Waist circumference		
Waist/Hip ratio		
Mid-abdomen circumference		
Sub scapular	Rt-	Rt-
	Lt-	Lt-
Above Iliac spine	Rt-	Rt-
	Lt-	Lt-
Sub scapular/Triceps Ratio		
Body fat index	Fat-	Fat-
	V.F-	V.F-
Body surface area		
Subcutaneous fat	Whole body-	Legs-
Skeletal muscle	Whole body-	Legs-

LAB INVESTIGATIONS

Sl. No.	Parameter		0 th Day	30 th Day	60 th Day	90 th Day
1	HbA1C					
2	Fasting Blood Sugar					
3	Post Prandial Blood Sugar					
4	Urine Sugar					
5	Fasting insulin					
6	HOMA-IR					
7	Lipid profile	Total cholesterol				
		HDL				
		LDL				
		VLDL				
		Serum Triglycerides				
8	Serum Creatinine					

Diabetes Quality of Life Measure (DQOL-as per DCCT)

Questionnaire	Satisfaction			
	V.Satisfied(1),Quite Satisfied(2), Satisfied(3), Little satisfied(4) Not satisfied(5)			
	0th day	30th day	60th day	90th day
Are you satisfied with the amount of time you take to control your diabetes?				
Are you satisfied with the amount of time you spend getting tested in general?				
Are you satisfied with the time it takes to verify your blood sugar levels?				
Are you satisfied with your current treatment?				
Are you satisfied with the flexibility of your diet?				
Are you satisfied with the apprehension your diabetes raises in your family?				

Are you satisfied with your knowledge about your diabetes?				
Are you satisfied with your sleep?				
Are you satisfied with your social life and friendship?				
Are you satisfied with your sex life?				
Are you satisfied with your work, school, or domestic chores?				
Are you satisfied with your body?				
Are you satisfied with the time you spend practicing physical exercises?				
Are you satisfied with your leisure time?				
Are you satisfied with your life in general?				
Score				
Questionnaire	Impact			
	Never(1), almost(2), sometimes(3), almost always(4), always(5)			
	0th day	30th day	60th day	90th day
How often do you feel the pain associated with your diabetes				

treatment?				
How often do you feel embarrassed about having to treat your diabetes in public?				
How often do you feel physically ill?				
How often does your diabetes interfere in your family life?				
How often do you have a bad night's sleep?				
How often do you find your diabetes is limiting your social life and friendship?				
How often do you feel bad about yourself?				
How often do you feel restricted by your diet?				
How often does your diabetes interfere in your sex life?				
How often does your diabetes deprive you from driving a car or operating a machine (eg. typewriter)?				
How often does your diabetes interfere with your physical exercises?				
How often do you miss work, school or domestic chores owing to your diabetes?				
How often do you explain yourself what it is to have diabetes?				
How often do you think your diabetes interrupts your leisure				

activities?				
How often do you feel embarrassed to tell others about your diabetes?				
How often do you feel bothered about showing diabetes?				
How often do you feel that, because of diabetes, you go to the restroom more often than others?				
How often do you eat something you should not instead of saying you have diabetes?				
Score				
Questionnaire	Concerns: Social/vocational			
	Never (1), Almost never(2), sometimes(3), almost always(4), always(5)			
	0th day	30th day	60th day	9th day
How often do you worry whether you will get married?				
How often do you worry whether you will have children?				
How often do you worry whether or not you will get the job you want?				
How often do you worry whether you will be refused an insurance?				

How often do you worry whether you will be able to finish your studies?				
How often do you worry whether or not you will lose your job?				
How often do you worry whether you will be able to go on vacations or to travel?				
Score				
Questionnaire	Concerns Related to Diabetes Never (1),almost never(1),sometimes(3),almost always(4), always(5)			
	0th day	30th day	60th day	90th day
How often do you worry whether you will pass out?				
How often do you worry whether your body looks different because you show diabetes?				
How often do you worry whether you will have complications dues to your diabetes?				
How often do you worry whether or not anyone will go out with you because of your diabetes?				
Score				

Total score	0 th day	30 th day	60 th day	90 th day

Calorie requirement calculation:**(i) Dietary Data:**(a) Dietary pattern: Veg (1) ☐ Mixed (2) ☐(b) Allergic to any food: Yes (1) ☐ No (0) ☐

If yes, please specify _____

(ii) Physical activity: Yes (1) ☐ No (0) ☐Type of Physical activity: Sedentary ☐ Moderate active ☐ Very Active ☐**Calorie calculation:**

- i. Obese inactive, sedentary men/women => 20 Kcal/Kg of present weight
- ii. Normal BMI, sedentary men/women => 22-25 Kcal/Kg of present weight
- iii. Normal BMI, active men/women => 30 Kcal/Kg of present weight
- iv. Thin/very active => 40 Kcal/Kg of present weight

Calorie Requirement = **ADVERSE EVENT PAGE**

Event description	/unknown	Date of onset	Severity	Out come	Serious during study	Intervention required
	Known	Date of resolution	code		Yes ☐	
		__/__/__		1 ☐		

	☐ Unknown ☐	____/____/____	a ☐ b ☐ c ☐	2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐	☐ No Code ____	
	Known ☐ Unknown ☐	____/____/____ ____/____/____	a ☐ ☐ ☐ b ☐ ☐ c ☐ ☐	☐ 1 ☐ ☐ 2 ☐ ☐ 3 ☐ ☐ 4 ☐ 5 ☐ 6 ☐	Yes ☐ ☐ No Code ____	
	Known ☐ Unknown ☐	____/____/____ ____/____/____	a ☐ ☐ ☐ b ☐ ☐ c ☐ ☐	☐ 1 ☐ ☐ 2 ☐ ☐ 3 ☐ ☐ 4 ☐ 5 ☐ 6 ☐	Yes ☐ ☐ No Code ____	

Severity code

1. Mild (causing no limitation of usual activities)
2. Moderate (causing some limitation of usual activities)
3. Severe (causing inability to carry out usual activities)

Outcome:

1= recovered / resolved without sequela, 2=recovering / resolving, 3=not recovered / not resolved 4= recovered/resolved with sequela 5= fatal, 6= unknown. The outcome of AE is not known

Seriousness code:

1=result in death, 2=life threatening, 3=requires hospitalization or prolongation of existing hospitalization 4=results in persistent or significant disability or incapacity, 5=is a congenital anomaly or birth defect

(Instructions for filling –put √ in appropriate boxes

MEDICINE DIARY (Day 30)

DAY	MORNING	NIGHT	COMMENT	DRUG
1				
2				
3				
4				
5				
6				
7				
8				

9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

MEDICINE DIARY (Day 60)

DAY	MORNING	NIGHT	COMMENT	DRUG
31				
32				
33				
34				
35				
36				
37				
38				
39				
40				
41				
42				
43				
44				
45				
46				
47				
48				
49				
50				
51				
52				

53				
54				
55				
56				
57				
58				
59				
60				

MEDICINE DIARY (Day 90)

DAY	MORNING	NIGHT	COMMENT	DRUG
61				
62				
63				
64				
65				
66				
67				
68				
69				
70				
71				

72				
73				
74				
75				
76				
77				
78				
79				
80				
81				
82				
83				
84				
85				
86				
87				
88				
89				
90				

Summary page

1 Check one reason for end of participation in the study

➤ Protocol completed

☐

➤ Subject withdrawn from the study

☐

2 Subject was withdrawn

☐

- At screening
- During the treatment

☐
ADVERSE EVENTS: (SUMMARY)

Investigators' Comments:

I hereby confirm that I had verified the data entered in this case record form and ensure that they are correct to the best of my knowledge.

		Signature	Date
Name of Chief investigator	Dr. Suketha Kumari		
Guide	Dr. B R Tubaki		
Co-guide	Dr. Rekha Patil		

PRAMEHA MUTRA PAREEKSHA (P: Present, A: Absent)

Features		0 th day	30 th day	60 th day	90 th day
Varna	Haridra meha				
	Shweta mutrata				
	Manjista /Lohita meha				
	Kala meha				
	Neela meha				
	Sarpimeha				
	Kshoudrameha				
Gandha	Sagandha(fruity)				
	Durgandha(bad,foul smell)				
Sparsha (Consistency)	Sandrameha(thick)				
	Tantumeha (thready)				
	Albuminuria				
	Udaka (Dilute urine)				
	Picchila(sticky)				
	Sheeta meha(Cold)				
	Avila mutrata(Turbid/cloudy)				
	Dhumayana mutrata(Smoky)				
Abnormal constituents	Sarktata(bloody)				
	Sikatata(Crystal)				
	Vasameha(Ketonuria)				

A. PRAMEHA PURVAROOPA ASSESMENT CHART

S.N	Feature	Score	0 th Day	30 th Day	60 th Day	90 th Day
	1.Madhuryamasya (Feeling sweetness in mouth)					
1.	None	0				
2.	Mild (Occasionally)	1				
3.	Moderate (Most time of the day)	2				
4.	Severe (Always)	3				
	2.Anga Shaitilya(flaccidity of muscles)					
1.	No anga shaithilya	0				
2.	Mild (shaithilya only few areas)	1				
3.	Moderate (flaccidity especially limbs)	2				
4.	Severe (Major areas)	3				
	3.Alasya (lazyness or indolence)					
1.	None does all routine and office work on time	0				
2.	Mild - tendency to postpone mildly	1				
3.	Moderate - tendency to postpone mildly	2				

4.	Severe – inability to carry on any work (office/household) in time	3				
	4. Shitapriyatwa (Desire for cold food & environment)					
1.	No desire	0				
2.	Mild(occasionally)	1				
3.	Moderate (during hot climate/2-3 times of the day)	2				
4.	Severe (All the time)	3				
	5.Anga gandha(Body odour)					
1.	No odour	0				
2.	Bad odour but not offensive	1				
3.	Detectable offensive odour, tolerable	2				
4.	Very strong odour even after using fragrances (use of deodorants or perfumes)	3				
	6.Shrama Swasa (Dyspnoea on exertion)					
1.	No dysnoea	0				

2.	Mild only when walking on an ascent or climbing steps more than 1 floor	1				
3.	Moderate when climbing one floor or walking for 500 mts on a flat surface	2				
4.	Severe cannot walk on flat surface more than 50 metres	3				
	7.Swedadikyata(perspiration)					
1.	Sweating only after heavy work and fast movement or in hot weather	0				
2.	Profuse sweating after moderate work and movement	1				
3.	Sweating after little work and movement (stepping ladder etc.)	2				
4.	Profuse sweating after little work and movement	3				
	8.Angasada (Physical Fatigability)					
1.	No fatigue	0				
2.	Fatigue on exercise	1				
3.	Fatigue on certain physical functioning	2				

4.	Fatigue at rest, interfering work family or social life	3				

B. PRAMEHA LAXANA ASSESMENT CHART

S.N	Feature	Score	0 th Day	30 th Day	60 th Day	90 th Day
1. Mutramadhurya (Glycosuria)						
1.	Absence of glucose in urine	0				
2.	Traces of Glucose in urine	1				
3.	+ glucose in urine	2				
4.	++ Glucose in urine	3				
2. Prabhuta Mutrata (Polyuria) - Frequency of urination						
1.	3 – 5 times per day, rarely at night	0				
2.	6 – 8 times per day, 1 – 2 times per night	1				
3.	9 – 11 times per day 3 – 4 times per night	2				
4.	> 11 times per day > 4 times per night	3				

	3. Pipasa-Adhikya (Increased Thirst)					
1.	No thirst	0				
2.	Drinking water satisfy the thirst, dryness of mouth, throat	1				
3.	Frequent feel to drink water	2				
4.	Severe (Feeling of severe thirst, waking up night to drink)	3				
	4. Kshudha-Adhikya (Increased Appetite)					
1.	No appetite/very poor	0				
2.	Occasional hunger/eating only few mouthful/one third plate	1				
3.	Two to three meals per day, comfortable, neither hungry nor full	2				
4.	Feeling hungry all the time with several hunger symptoms	3				
	5.Klama (mental fatigue)					
1.	No fatigue and mental effort not reduced	0				
2.	Fatigued quickly but still able to make some mental effort	1				

3.	Fatigue on certain physical functions	2				
4.	Fatigue at rest, interfering work family or social life	3				
6.Purishabaddhata (Constipation)						
1.	Stool passes as per normal schedule	0				
2.	Passes stool with strain, sometimes takes purgative	1				
3.	Passes stool after more than 24 hours, frequently takes purgative	2				
4.	Passes stool after gap of one day, normal purgatives does not work	3				

ANNEXURE 4: PHD PROGRESS REPORT

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)
Accredited 'A+' Grade by NAAC (3rd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 FAX: 0831-2493777 Web: <http://www.kledeemeduniversity.edu.in> E-mail: info@kledeemeduniversity.edu.in

Ref. No. KAHER/AA/23-24/D- 319-3 25th August 2023

Ph. D. PROGRAM

Evaluation of Six Monthly Reports submitted by the Candidate

Name of the Ph.D. Scholar : Dr. Suketha Kumari

Name of the Guide : Dr. B.R. Tubaki
Dr. Rekha S. Patil

Batch/Category/Faculty : 2019 / Full-Time / Ayurveda

Topic : Efficacy Of Integrated Ayurveda Treatment Protocol In
Uncontrolled Type 2 Diabetes Mellitus: A Randomised
Controlled Clinical Trial

Report	Excellent	Good	Satisfactory	Poor
I			✓	
II			✓	
III			✓	
IV			✓	
V			✓	
VI			✓	
VII			✓	
VIII			✓	

Note: Only when three reports are satisfactory and if the candidate has published articles as per rules then only the candidate is permitted to present second Open house seminar followed by submission of thesis.



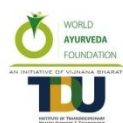
(Dr. Roopa M. Bellad)
Director, Academic Affairs

Cc to : : Dr. B.R. Tubaki, Professor of Kayachikitsa, Shri. B.M.K. Ayurveda Mahavidyalaya,
Belagavi-Guide
Dr. Rekha S. Patil, Professor of Medicine, J. N. Medical College, Belagavi-Guide

NB: Research scholars are hereby informed in future to strictly enclose the source of documents to review half yearly reports.

ANNEXURE 5: PUBLICATION

Journal of Ayurveda and Integrative Medicine 13 (2022) 100512



Contents lists available at ScienceDirect

Journal of Ayurveda and Integrative Medicine

journal homepage: <http://elsevier.com/locate/jaim>

Case Report

Efficacy of Integrated Ayurveda treatment protocol in type 2 diabetes mellitus – A case report

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Yoga

Case report

ABSTRACT

Type 2 Diabetes Mellitus (T2DM) is a growing global concern having reached the epidemic proportion in most countries. Achieving glycaemic control decreases the risk of macrovascular and microvascular complications in T2D. To achieve and maintain good glycaemic control, lifestyle changes and pharmacological treatment is necessary. Pharmacological management of T2DM have some limitations as it may lead to vit-B12 deprivation, hypoglycemia, increased cardiovascular risk etc. Treatment algorithm that include integration of Ayurvedic treatment & diet, Panchakarma therapies and Yoga will ensure good glycaemic control and reduce the progression of complications. Diagnosed cases of T2DM without intervention of conventional pharmacological drugs will be safe and beneficial. A female patient aged about 52 years visited to diabetic specialty OPD with the following complaints: increased micturition frequency, vaginal itching, fatigue and increased thirst. Patient reported weight gain in past 1 year, was not on any conventional antidiabetic medication. Her HbA1c status confirmed diagnosis of T2DM. Patient was treated with a course of *nitya virechana* (medicated purgation) and *Sarwanga Udwartana* (Dry medicated powder rubbing whole body) for the duration of 7 days along with ayurveda medicines for 1 year. Patient was prescribed Ayurvedic diet and Yoga practices throughout the intervention. This case report reveals the protocol based integrated Ayurveda and Yoga practices for diagnosed case of T2DM without causing any untoward effect along with reversal of the diabetes.

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1. Introduction

Type 2 Diabetes Mellitus (T2DM) is the most common form of DM characterized by hyperglycaemia, insulin resistance and relative insulin deficiency [1]. According to the International Diabetes Federation (IDF), approximately 415 million adults between the ages of 20–79 years had diabetes mellitus in 2015. T2DM is proving to be a global public health burden as this number is expected to rise to 615 million by 2040 [2]. It is estimated that by 2030 this would have risen to 552 million [3]. *Ayurveda* describes a set of complex clinical disorders with frequent abnormal micturition, collectively called *Prameha* (*Diabetes Mellitus*), which correlate in many ways with obesity, metabolic syndrome, and diabetes

mellitus [4]. Type 2 DM is analogous to *Sthula pramehi* (Obese Diabetic) which is also known as *Apathyanimittaja Prameha* or acquired type of diabetes resulting due to faulty lifestyle [5]. *Samshodhana* (purification) is the best treatment for the elimination of *Doshas*. *Vagbhata* has mentioned that *Doshas* should be eliminated through the nearest pathway [6]. *Ayurvedic* medications with lifestyle modifications contribute to desired clinical outcome as proper diet and management of daily routines will remove the causative factors of disease and helps in preventing progression of the disease. *Yoga* has been practiced since ancient times to manage the physiology of the body. This not only improves the flexibility but also improves the function of both endocrines and exocrine glands of the body. Various studies have reported that *Yoga* has a positive impact in the management of Type 2 diabetes. Different *Asanas* such as *Surya Namaskara* helps in insulin production and improvement of digestive fire [7].

Present case report deals with the *Ayurvedic* approach of *Panchakarma*, *Ayurvedic* medications, *Yoga*, *Pathyaha* and lifestyle

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counseling. All of these helped to achieve desired clinical outcome without causing any side effects and there was no recurrence of symptoms in the follow up period of about one year.

2. Patient information

A female patient aged about 52 years, who was homemaker visited to diabetic specialty OPD on 14/01/2018 with the following complaints: increased frequency of micturition for 1 month (5–6 times during day and 1–2 times at night), fatigue since 1-year, increased thirst from 2 months which was progressive in nature and vaginal itching from 15 days. Patient had noticed weight gain (approx 10 kg's) in a period 12 months. Patient had hypertension for 8 years and was on antihypertensive medications. Patient had no past history of Type 2 DM and no medication history. No family history of DM was found. Timeline of the case is summarized in Table 1.

3. Clinical findings

Patient had frequent micturition, associated with fatigue, thirst and vaginal itching. Patient also had progressive weight gain. Personal details and habits of the patient include lifestyle with a lot of sitting and lying down, with minimal physical activity and sedentary lifestyle. On examination, patient had abdominal obesity and well-nourished body. She had normal menstrual and obstetric history include Gravida 2, live births 2 and no abortion history (G₂L₂A₀). The patient was 152 cm tall and weighed 82 kg and waist circumference and BMI of the patient are 38 inches and 35.5 Kg/m² respectively. Assessment on 14/01/2018 revealed FBS-174 mg/dl, PPBS-208 mg/dl, and HbA1c-8.8 together these variables confirmed the diagnosis of of T2DM. Patient was found to be dull in action, lethargic with disturbed sleep and moderate appetite, *Krura koshta* (bowel hard to purgate) with increased micturition. Patient had *Pitta Kapha Prakriti* (body constitution) which was assessed using 'CCRAS Prakriti assessment scale' available on http://www.ccras.res.in/ccras_pas/

Table 1
Timeline of the case.

Year	Clinical events and Intervention
2016 to 2017	Weight gain issue (Approximately 10 kg)
Jan 2017	Started developing fatigue, lethargy
November 217	Increased thirst
December 2017	Increased micturition frequency
January 2018	Intense vaginal itching
14/01/18	FBS, PPBS, HbA1c confirmed the diagnosis of T2DM
15/01/18	IPD admission
15/1/18 to 21/1/18	Undergone purgation therapy and Udwartana procedure
	Ayurveda Pathyahara and Yoga
22/1/18	Discharged
23/1/18 to 16/4/18	Ayurveda medication continued; Pathyahara & Yoga was routinely Practiced.
	Remarkable improvement in Biochemical parameters
	Reached Asymptomatic phase
17/4/18 to 3/11/2019	Investigation report suggest reversal of Diabetic to prediabetic stage
	Weight loss: 10 Kg
	Asymptomatic phase
	Good energy level
	Stopped Ayurveda Medication
	Advised to continue Pathyahara and Yoga.

4. Diagnostic focus and assessment

Diagnosis was based on clinical symptoms and biochemical parameters. Patient complained of experiencing increased frequency of micturition, thirst, fatigue, marked obesity and was diagnosed with *Prameha* [8,9]. Based on history and examination, patient presented with typical features of *madhumeha* a type of *Vataja prameha*. We found *Pitta* and *Kapha* in association with it. While analysing the symptoms, thirst indicated *Pitta* dominant *Madhumeha* (8. Chi 28/61) whereas marked obesity, fatigue, lethargy indicated *Kapha* dominant *Madhumeha* (8. Su.20/17) (8. Chi 28/62). Hence diagnosis can be made as *Kapha-pittavrata Madhumeha* (*Kapha-Pitta* dominating *Madhumeha*). In Type 2 DM, presence of hyperglycaemia for months or years eventually causes the extreme thirst, frequent urination, tiredness, nausea and dizziness [10]. Since symptoms were present for more than a month, patient was obese and had absence of autoimmune diseases history [11] along with lab investigations of following variables: fasting blood sugar, post prandial blood sugar and Glycosylated haemoglobin, all confirmed diagnosis of T2 DM.

5. Therapeutic intervention

Kapha dosha (along with other 2 *doshas*) and *Medo dhatu* will dominate in *Madhumeha* [12]. Shodhana (detoxification therapy) is the first line of treatment indicated in classics. For *Kapha* and *Meda* vitiation, external treatment modalities such as *Abhyanga* (oil massage), *Udwartana* (dry powder rubbing) etc, are indicated. In this case, patient underwent for a course of *Nitya Virechana* (daily purgation therapy) with *Triphala churna* 10 gms every night for duration of 7 days. *Sarvanga Udwartana* with *T. churna* (QS) was performed for the duration of 7 days. After 7 days of above treatment, internal medication were prescribed which included *Nishakatakadi Kashaya* (contains ingredients such as *Nisha*, *kathaka*, *amalaka*, *Paranti*, *Iodhra*, *badhrika*, *Peetika*, *usira*) 15 ml tid, *Amalakyadi* compound (*Amalaki* + *Godshura* + *Sariva* + *Guduchi* + *Chopachini* + *Haridra* + *Daruharidra* + *Yashtimadhu churna* – each 10 gms + *Vanga bhasma* (2.5 gms) 1tsf BD with warm following food consumption were prescribed for a duration of 1 year (Table 2).

Ayurveda diet explained in *Madhumeha* was planned. Diet was customized as per patients traditional food intake, regional availability etc. (Table 3).

Yoga protocol included wide range of components which could be done in short duration starting from breathing practices to meditation. Patient underwent stretch breathing and loosening practices for five minutes each before advancing to *suryanamaskar* (5 minutes) and varieties of *asanas*. *Ardakati chakrasana*, *parivrattra trikonasana*, *vakrasana*, *arda matsyendriyasana*, *bhujangasana*, *dhanurasana*, *pawanamuktasana* and *matsyasana* are the *asanas* advised for 10 minutes each. *Kapala bhati* was practiced regularly which was then followed by *pranayama* like *nadi shuddi*, *bhramari* and *om chanting* for 10 minutes and cyclic meditation at the end. Relaxation technique was also part of protocol after vigorous *asanas* and *kriya*.

No any adverse events occurred during the course of treatment.

6. Follow up and outcome

Biochemical parameters were assessed at each follow up and improvement was observed in each parameter. Follow up treatment and improvement in lab parameters are summarised in Table 4. Increased micturition frequency, thirst, fatigue, vaginal

Table 2
Ayurvedic management on the case of T2DM.

Panchakarma Procedure	Method of Preparation	Method of administration	Treatment Duration	
Nitya virechana with Triphala Churna	10-g Powder of Triphala	Powder of Triphala 10 g administered after 20 min of night meal along with warm water.	7 days	
Sarvanga udwartana with Triphala Churna	Powder of Triphala-Q. S Approximately 200 g per day	Rubbing of the dry powder of Triphala to whole body empty stomach in the morning.	7 days	
Oral medication	Details of Oral medication(ingredients)	Dose	Anupana	Treatment duration
Nishakatakadi Kashaya	Nisha (<i>Terminalia chebula</i> Retz.), kathaka (<i>senegalia catechu</i>), amalaka (<i>emblica officinalis</i> linn.), Paranti (<i>ixora coccinea</i>), lodhra (<i>symplocos racemosa</i>), badhrika (<i>aerva lanata</i>), Peetika (<i>Salacia oblango</i>), usira (<i>chrysopogon zizanioides</i>)	15 ml Tid	Luke warm water	1 year
Amalakyadi compound	Amalaki (<i>emblica officinalis</i> linn.), Gokshura (<i>tribullus terrestris</i>), Sariva (<i>hemidesmus indicus</i>), Guduchi (<i>tinospira cordifolia</i>), Chopachini (<i>smilax glabra</i>), Haridra (<i>Curcuma longa</i> Linn.), Daruharidra (<i>berberis aristata</i>), Yashtimadhu (<i>glycyrrhiza glabra</i>), Vangabhasma (tin)	1tsf BD	Luke warm water	1 year

itching were reduced. Her energy level was improved and healthy weight loss of about 1–2 kg per month was observed (Approximately 10 kgs in a period of 1 year).

7. Discussion

Patient treated with traditional approach i.e Panchakarma procedures, oral medicines, Ayurvedic Pathyaha and Yoga intervention.

Samshodhana (purification) and Avaranahara (removal of body channels' occlusion) treatment was adopted on the basis of Samprapti (pathogenesis), Nityavirechana (medicated purgation) with *T. churma* – 10 gms & Sarvanga Udwartana (rubbing with dry powder) with *T. churma* (QS) was done for 7 days. The *kapha* (phlegm) increasing etiologies will also increase *Meda*, this *Medas* when vitiated deposits as *Durmedas* (adipose) (8. Su.23/8–9). The line of treatment for *Medoja roga* (diseases occurred in vitiated fatty tissue) is use of *Shleshma-medohara* (reduction of *Kaphadosha* and fatty tissue), *Vataghna* (pacifying *Vatadosha*), *Ruksha-Ushna-Tikshna Virechana* (medicated purgation with rough, hot potency and penetrating properties) [13].

Udwartana i. e, rubbing the medicated powder over body in the opposite direction of the hair root. It causes *Kapha-meda vilayana* (liquefaction of *Kapha* and *Medas*), *sthirata* of body (stability), *twak prasadana* (nourishment of skin) [14].

Virechana was performed using *Triphala* which has the quality to eliminate both *Pitta* and *Kapha*(13. Su.6/159). It is indicated in *Prameha*, also acts as mild laxative which aids in weight loss. At the same time, *udwartana* using *Triphala* was done because body fat and weight loss can be achieved by usage of *Triphala*. It was found to be effective in diabetes as it reduces blood sugar and insulin levels because of its hypoglycaemic potentials [15]. Hence *Triphala* was selected for both *udwartana* and *nitya virechana*.

Nishakatakadi Kashaya 15 ml tid was used due to its antidiabetic action [16]. *Amlakyadi* compound 1 tsf bd was used in which ingredients such as *Gokshura* (*Tribullus terrestris*) which possess

basthishodhana (cleansing) effect reduces *Avarna* of *Kapha* and *Meda* in the microcirculation of kidneys [17]. *Vanga bhasma* also helps to pacify *Kapha* and is useful in diabetes [18]. *Amlaki* (*Emblica officinalis* G.) and *Guduchi* (*Tinospora cordifolia*) have been used for their anti-inflammatory and antioxidant action [19,20]. *Daruharidra* [21] (*Berberis aristata*) acts by decreasing oxidative stress hence useful in this condition. To attain immunomodulatory effect, *Yashtimadhu* (*Glycyrrhiza glabra*) was used and it is also an anti-diabetic [22,23]. Combined prescription of *Nishakatakadi Kashaya* and *Amlakyadi* compound had proven to be synergistic with former having disease specific effects and latter had helped in breaking the *samprapti* (Pathogenesis) of the disease.

Dietetic regimen that includes exclusion of foods that are high in sugar, including *Pathyaha*, eating smaller portions, throughout the day, adding variety of whole grain foods, fruits and vegetables everyday helped in maintaining the blood sugar levels in desired range [24]. Millets which contain high proportion of soluble dietary fibres case reduction in gastric emptying and absorption of glucose after a meal, resulting in improved glucose tolerance. Intake of millets helps with satiety but yet its not be high in calories (*guru ch aatarpana*). Lotus seeds (*Makhane* as snacks) contain some alkaloids and flavonoids with anti-obesity and hypolipidemic effects [25].

Yoga practice was prescribed from a prevalidated standard protocol which is proven to be effective as well as it efficient for the patient in terms of cost, time and efforts. Many studies have used discrete yoga protocols that are proven to be effective when used for longer duration. The protocol used for the patient was specifically chosen for achieving results in relatively shorter duration of time. Certain breathing practices, loosening practices, *Asanas*, *kriyas*, *Surya namaskara*, *Pranayama*, deep relaxation techniques and meditations were advised in which the slow breathing technique in *pranayama* causes comprehensive changes in body physiology by controlling the autonomic nervous system [26]. *Suryanamaskar* regularizes the flexibility and postural balance mechanism [27] which is directly helpful to counteract obesity. *Pranayama* alone has shown to offer

Table 3
Ayurveda Pathyahara.

Sample Menu Plan [1200 Kcal (+ or – 50 Kcal) Per day [Protein: 45 gm/day (+ or – 5 g), CHO: 195 gm, Fat: 26.5 gm/day]						
Timing Food Diary	Menu				Serving	
Morning Drink B/w 6.30 am – 7 am (Any One)	1. Herbal Infused Drink 2. Ginger Lemon water 3. Cinnamom water 4. Chia seed Water				150 ml (1 glass) 100 ml 100 ml 100 ml	
8 am – 9 am Breakfast options (Any one)	1. Broken wheat vegetable upma (Daliya Upma) 2. Besan Dosa(Tomato Omlette) + Herbal Chatni + Sambar 3. Barley/Whole wheat chapati + Herbal/coconut Chatni + Sambar 4. Millet Dosa/Idli + Herbal/coconut Chatni + Sambar 5. Millet Vegetable Upma 6. Moong dosa + Herbal/coconut Chatni + Sambar Breakfast with Herbal/Cardamom/Green Tea without sugar				1 bowl/1 plate 1 in no 2 tbsp 1 wati 1 in no 2 tbsp 1 wati 1 in no/2 in number 2 tbsp 1 wati 1 bowl/1 plate 1 in no 2 tbsp 1 wati 1 cup	
Mid-Morning Snack	1. Medicated Buttermilk (Spiced with Ginger, Pepper, Rock salt and Jeera)				1 glass (150 ml)	
Lunch 1pm to 2 Pm	Mix Veg Salad (Raw-spiced with pepper powder and Rock Salt) +Jowar/Bajra Roti +Vegetable Sabji +Boiled Pulses Sabzi/Junka/moong Dal +Peanut/Methi/Flax Chatni				1 bowl 1 in number 1 wati 3/4th katori 1 tbsp	
Mid Evening Snack 4.30 pm – 5 pm (Option-Any one)	1. Apple/unripened Pear Fruit +Almond +Walnut + Green Tea/Lemon tea without Sugar 2. Ghee Roasted makhanas added with Rock salt + Turmeric (Lotus flowers) +Almond +Walnut + Green Tea/Lemon tea without Sugar 3. Churmura + Unsalted Roasted Pea nut + Green Tea/Lemon tea without Sugar				1 medium Size 4 2 1 cup 1 cup 2 2 1 cup 1 plate/1 handful 1 cup	
Dinner (7 pm – 8 Pm) (Option-Any one)	1. Salad (spiced with lemon, pepper, rock salt) + Herbal Soup 2. Millet Kichdi + Herbal Raita 3. Millet Rice + moong dal + Herbal Raita 4. Salad (spiced with lemon, pepper, rock salt) + Moong Soup (spiced with Pepper and Rock Salt) + vegetable pulao 5. Moong Khichdi + Salad (spiced with lemon, pepper, rock salt)				1 bowl 1 bowl 1 bowl ½ Wati 1 Katori 1 wati ½ wati 1 bowl 1 bowl (150 ml) 1 bowl 1 bowl 1 bowl	
Menu	Exchange	Gram	Calorie	Protein	CHO	Fat
Cereals	3	90	300	9	54	2.1
Rice	2	60	200	5	46	0.4
Pulses	2	60	180	13	30	1
Buttermilk	1	100 ml	26	2	2	1
Curd	1	100	62	4	4	3
Vegetable	4	400	160	8	26	1.7
Fruits	1	50 – 75	50	1	10	–
Oils and Fats	3	15	135	–	–	15
Nuts and oilseeds	1	20	100	3.5	5	7.5
Total	-	-	1213 kcal	45.5 gm	177 gm	31.7 gm

*Note: Diet was customized as per the patient's traditional food intake, regional availability etc.

number of beneficial health effects including stress relief and improvement in cardiovascular functions [28]. Yoga causes Para-sympathetic activation which in turn helps to achieve overall metabolic and psychological improvement through stress reduction,

increased insulin sensitivity, and improved glucose tolerance and lipid metabolism [29,30].

This integrated approach which contains oral Ayurvedic drugs, Panchakarma procedures, Yoga protocol and Ayurveda diet were

Table 4
Showing treatment protocol and improvement in Lab parameter.

Visits	Treatment	FBS, PPBS, HbA1c
1.16/4/2018	1.Nishakatakadi Kashaya 15 ml TID 2.Amalakyadi compound 1tsf BD	FBS: 134 PPBS:167 HbA1c: 7.8
2.17/7/2018	1.Nishakatakadi Kashaya 15 ml TID 2.Amalakyadi compound 1tsf BD	FBS: 102 PPBS: 142 HbA1c: 7
3.14/10/2018	1.Nishakatakadi Kashaya 15 ml TID 2.Amalakyadi compound 1tsf BD	FBS:98 PPBS: 112
4.3/11/2019	1.Nishakatakadi Kashaya 15 ml TID 2.Amalakyadi compound 1tsf BD	FBS: 98 PPBS: 112 HbA1c: 6
BT and AT comparison in Lab Parameters		
Parameters	Before Treatment (14-1-18)	After treatment (19-1-19)
FBS	174 mg/dl	85 mg/dl
PPBS	208 mg/dl	102 mg/dl
HbA1C	8.8	6

helpful in treating the patient of DM. This approach may be taken into consideration for further research in DM.

8. Conclusion

Integrated *Ayurveda* treatment protocol containing *Ayurveda* medicines, *panchakarma* intervention, *Ayurvedic pathydhara* and *yoga* practise was helpful in treating type 2 diabetes mellitus. This approach can be adopted for T2DM treatment and research.

8.1. Patient perspective

The patient was satisfied with her health improvement. She was pleased with the healthy weight loss and retaining it for 4 months along with improvement in her energy level. Improvement in sleep quality and digestion, contributed to her perception of improved quality of life and recovery as a result of this holistic approach.

8.2. Patient consent

Written permission for publication of this case study had been obtained from the patient.

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None.

Conflict of interest

None.

Author contributions

Suketha Kumari: Software, Validation, Formal analysis, Writing – review and editing.

Laxmikant SD: Conceptualization, Methodology/Study design, Investigation, Resources, Writing – original draft, Writing – review and editing, Visualization, Supervision.

Sonika B: Conceptualization, Investigation.

Suman Khanal: Conceptualization, Investigation, Data curation.

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Efficacy of Integrated Ayurveda Treatment in Type 2 Diabetes mellitus with special reference to *Prameha*: A Randomised controlled Trial

Research Article

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Abstract

Background: Diabetes mellitus (DM) is marked by persistent hyperglycemia, often due to insulin resistance. Type 2 diabetes mellitus (T2DM) constitutes 90% of the cases and shares similarities with *Prameha*, a disorder characterised by frequent urination. **Aims and objectives:** This study aimed to compare Integrated Ayurveda Treatment (IAT) with standard diabetic treatment for *Prameha*. **Materials and methods:** A randomised, controlled open-label trial involved 200 T2DM subjects with HbA1C above 7%, taking metformin (≥ 1 g /day). They were assigned to Standard Dietary Treatment (SDT) or IAT. SDT comprised metformin, dietary, and lifestyle modifications, while IAT included metformin with Ayurvedic medicine, specific Ayurveda diet, and yoga. **Observation and result:** Observations favoured Ayurveda treatment over standard diabetes treatment for most *Prameha* preliminary symptoms (*purvarupa*). Regarding *Prameha rupa* (symptoms), IAT significantly outperformed than SDT. Also, Ayurveda treatment group, led to improvements in HbA1C, fasting and postprandial blood sugar, and insulin resistance parameters compared to standard treatment group. **Conclusion:** Integrating *Madhumeha ghana vati*, ayurveda diet, and yoga with standard treatment yielded positive subjective and objective outcomes for *Prameha*, without significant adverse events. This suggests the potential benefits of combining Ayurvedic approaches with conventional care in managing *prameha*.

Keywords: *Prameha*, *Purvaroopas*, *Madhumehari ghana vati*, *Pathyahara*, Type 2 diabetes mellitus, Metformin.

Introduction

Diabetes mellitus (DM) is a chronic metabolic illness where persistent hyperglycemia is a hallmark. It might be brought on by decreased insulin secretion, resistance to insulin's peripheral effects, or both. Ninety percent of all instances of diabetes are caused by type 2 diabetes mellitus (T2DM) due to insulin resistance (1). Previous research considered insufficient diabetes control (uncontrolled T2DM) as glycated haemoglobin (HbA1C) of $>7\%$ (2). An estimated 462 million people worldwide suffer with T2DM (3). According to predictions from 2019, there were 77 million diabetics in India; by 2045, that number is predicted to reach over 134 million (4). The crucial elements of treatment for type 2 diabetes are lifestyle modification and goal-setting, pharmaceutical interventions, self-management and support (5). Anti-diabetic medications include biguanides like metformin, insulin secretagogues such

as sulfonylureas, and insulin sensitisers such as thiazolidinedione's. Among these, metformin is the first-line pharmacotherapy for T2DM (6). However, following medications, which have potential side effects, makes treatment compliance difficult. Ayurveda classics define *Prameha* as a set of complex clinical disorders characterised by frequent abnormal micturition, with the aetiology involving genetic predisposition as well as improper diet and lifestyle. The clinical conditions described in *Prameha* have much in common with T2DM. Ayurveda classics describe etiological factors of *prameha* as sedentary activities, early introduction of milk and its products, animal feed cultivated especially in swampy areas, newly harvested grains and refined sugars etc. (7) which has have more similarity with aetiology of T2DM.

Ayurveda recommend different treatment modalities in *prameha* such as *nidana parivarjana* (preventive strategies), *shodana* (Detoxification), *shamana* (internal medication) and *Pathyapathya* (diet and lifestyle restriction). In *Prameha*, aggravated *Kapha dosha* does vitiation of *medas* (adipose tissue), *mamsa* (muscle tissue) and *kleda* (fluid). Excessively aggravated *medas* leads to *Purvarupas* (premonitory symptoms) of *Prameha*. Vitiated *kleda* produces urinary symptoms(8). *Madhumehari ghana vati* [MGV], an Ayurvedic poly-herbal formulation which has 10

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Suketha Kumari et al., Efficacy of Integrated Ayurveda Treatment in Type 2 Diabetes mellitus with special reference to Prameha

ingredients such as *Meshashringi* (*Gymnema sylvestre* R. Br.), *Vijayasara* (*Pterocarpus marsupium* Roxb.), *Jambu* (*Syzygium cumini* Linn.), *Amalaki* (*Emblica officinalis* Gaertn.), *Hareetaki* (*Terminalia chebula* Retz.), *Vibheetaki* (*Terminalia belirica* Roxb.), *Haridra* (*Curcuma longa* Linn.), *Guduchi* (*Tinospora cordifolia* Willd.), *Tamalapatra* (*Cinnamomum tamala* (Buch. Ham.) and *Daruharidra* (*Berberis aristata* DC.) which are known to have benefits in *prameha* by reversing the pathogenesis (9, 10). MGCV, a poly-herbal formulation is a product of our affiliated pharmacy and has shown beneficial effects in our clinical settings. An experimental trial conducted on diabetes induced animals, administered with MGCV for 28 days showed significant reduction of fasting blood glucose (FBG) compared to diabetic treated group animals (11). Herbs of MGCV have anti-hyperglycaemic, lipid lowering (12), antioxidant (13) and insulin sensitising (14) properties. *Ayurveda pathyahara* contain food which are light to digest, *medohara* therapeutic food components and easy & have palatable nature. Yoga being lifestyle intervention proved beneficial in reducing body weight, useful in glycemic control. It also emphasises on relaxation, meditation, and deep breathing, may have special relevance with quality of life of T2DM (15). Hence, the current study was planned with the objective to evaluate the efficacy of Integrated *ayurveda* treatment [IAT] which contain *Ayurveda* medication [MGCV], *Pathyahara* and *Yogic* intervention in *Premea* with special emphasis on quality of life and subjective profile (*prameha purva rupa & laxana*).

Materials and methods

Participants

It was a randomised controlled trial conducted on 200 subjects at KLE *Ayurveda* hospital, Belagavi, Karnataka, India.

Inclusion criteria

- Subjects with Type 2 diabetes who were between the ages of 18 and 70
- Subjects with inadequate blood glucose control (HbA1c: 7 to 10.5%) while receiving steady metformin medication (≥ 1 g/day) were enrolled.
- Participants quality of life and clinical condition assessment based on *Ayurveda* parameter was the main objective considered in this study (Table no.1).

Exclusion criteria

- Subjects with cardiovascular disorders
- Subjects with uncontrolled hypertension ($\geq 140/90$ mmHg)
- Subjects with micro vascular complications of T2DM

The medical trial received approval from the KAHER ethical committee for human subjects (Ref ID: KAHER/EC/20-21/001/11) with prospective CTRI Registration Number: CTRI/2020/12/029762. The CONSORT statement guideline was followed when reporting the study's findings.

Table 1: *Prameha purva rupa* assessment parameter with grading

Si.no	<i>Purva rupa</i>	0	1	2	3
1	<i>Madhuryamasya</i> (Feeling sweetness in mouth)	None	Mild (Occasionally)	Moderate (Most time of the day)	Severe (Always)
2	<i>Anga Shaitilya</i> (flaccidity of muscles)	No anga shaitilya	Mild (shaitilya only few areas)	Moderate (flaccidity especially limbs)	Severe (Major areas)
3	<i>Alasya</i> (laziness or indolence)	None does all routine and office work on time	Mild - tendency to postpone mildly	Moderate - tendency to postpone frequently	Severe - inability to carry on any work (office/ household) in time
4	<i>Shitapriyatva</i> (Desire for cold food & environment)	No desire	Mild (occasionally)	Moderate (during hot climate/2-3 times of the day)	Severe (All the time)
5	<i>Anga gandha</i> (Body odour)	No odour	Bad odour but not offensive	Detectable offensive odour, tolerable	Very strong odour even after using fragrances (use of deodorants or perfumes)
6	<i>Shrama Swasa</i> (Dyspnoea on exertion)	No dyspnoea	Mild only when walking on an ascent or climbing steps more than 1 floor	Moderate when climbing one floor or walking for 500 mts on a flat surface	Severe cannot walk on flat surface more than 50 meters
7	<i>Swedadikyata</i> (perspiration)	Sweating only after heavy work and fast movement or in hot weather	Profuse sweating after moderate work and movement	Sweating after little work and movement (stepping ladder etc.)	Profuse sweating after little work and movement
8	<i>Angasada</i> (Physical Fatigability)	No fatigue	Fatigue on exercise	Fatigue on certain physical functioning	Fatigue at rest, interfering work family or social life



Prameha rupa assessment parameter with grading					
1	Mutramadhurya (Glycosuria)	Absence of glucose in urine	Traces of Glucose in urine	+ Glucose in urine	++ Glucose in urine
2	Prabhuta Mutrata (Polyuria) - Frequency of urination	3 – 5 times per day, rarely at night	6 – 8 times per day, 1 – 2 times per night	9 – 11 times per day 3 – 4 times per night	> 11 times per day > 4 times per night
3	Pipasa-Adhikya (Increased Thirst)	No thirst	Drinking water satisfy the thirst, dryness of mouth, throat	Frequent feel to drink water	Severe (Feeling of severe thirst, waking up night to drink)
4	Kshudha-Adhikya (Increased Appetite)	No appetite/very poor	Occasional hunger/ eating only few mouthful/one third plate	Two to three meals per day, comfortable, neither hungry nor full	Feeling hungry all the time with several hunger symptoms
5	Klama (mental fatigue)	No fatigue and mental effort not reduced	Fatigued quickly but still able to make some mental effort	Fatigue on certain physical functions	Fatigue at rest, interfering work family or social life
6	Purishabaddhata (Constipation)	Stool passes as per normal schedule	Passes stool with strain, sometimes takes purgative	Passes stool after more than 24 hours, frequently takes purgative	Passes stool after gap of one day, normal purgatives does not work

Research design

The research was a single-centric, open-label, parallel group, randomised, standard controlled trial. A block size of two was used for block randomisation. Random numbers produced by a computer were used to form allocation sequences. Based on statistical calculation, it was found that 80 participants in each group found sufficient. However, considering the 20% attrition rate, sample size of 100 in each group was taken within a 95% confidence interval and 5% correction error.

Intervention

As per the randomisation, 200 subjects equally divided into two groups: Group A has Standard diabetic treatment (SDT) and group B has Integrated Ayurveda treatment (IAT). SDT intervention had standard dietary advice, lifestyle intervention along with drug metformin ($\geq 1\text{g/day}$). Standard dietary advice was as approved by American diabetic association (ADA) (16) which was customised as per local and regional eating practices. A top dietician who has worked with diabetes for more than ten years approved the diet plan. Lifestyle change advice includes any sort of activity for at least 150 minutes per week (or 3 to 7 days per week, with no more than 2 days without exercise) (17). IAT group had metformin ($\geq 1\text{g/day}$), add on intervention of Ayurveda polyherbal drug called *Madhumehari ghana vati* (MGV) 3 grams per day administered as 500 mg *ghana* (thick extract) 2 tablet 3 times a day after meal with water, Ayurvedic therapeutic diet and yoga. MGV had 10 herbs procured from reliable sources and prepared (Table no.2& 3). The tablets were manufactured at a recognised KLE Ayurvedic pharmacy using Good Manufacturing Practices (GMP) in compliance with normal procedures. As per the specified quantity, all coarse powders were taken in *khalva yantra* (mortar &

pestle), and a homogenous mixture was prepared. The drug mixture was taken into a stainless steel container and soaked in eight parts of tap water for 12 hours. The overnight-soaked drug mixture was kept boiling on a moderate fire till it was reduced to one-fourth quantity. A pleasant odour of *kashaya* was observed during boiling. Filtered and kept aside. The *kashaya* was taken into a stainless steel vessel and kept for boiling. The boiling was continued until it attained a semisolid consistency. After attaining semisolid consistency, the vessel was removed from the gas. It was taken on a thick polythene sheet when it was warm and kept in the shade for drying. After drying completely, it was powdered to a size of 500 mg. The *Vati* was prepared and stored in an airtight container. In the Ministry of AYUSH-approved ASU (*Ayurveda, Siddha, Unani*) drug testing laboratory at KAHER's Shri BM Kankanwadi Ayurveda Institute Belagavi, raw drug authentication and physiochemical standards of tablets were conducted. Ayurveda dietary plan is prepared after a thorough literature review and with incorporation of local eating practices. This consists time restricted therapeutic eating, herbs processed drinks, and the millet based meals and integration of more greens with allowance of all tastes to make it more palatable and interesting. The following factors were taken into consideration when determining the *hitatwa* (wholesome) and *ahitatwa* (unwholesome) of food: *prakrati* (food nature), *karana* (processing method), *raashi* (quantity), *desham* (habitat), *kalam* (time or climatic factor), *samyoga* (combination), *upayoga samstha* (rules of food intake), and *upayokta* (user compatibility). Food which pacifies *kapha*, *kleda* and *medas* were incorporated. The diet regimen was more broadly appealing and focused on *dosha* balancing. [Table no.4].



Suketha Kumari et al., Efficacy of Integrated Ayurveda Treatment in Type 2 Diabetes mellitus with special reference to Prameha

Table 2: Botanical name, part used and proportion of the Madhumehari ghana vati

Sl.no	Sanskrit name	Botanical name	Part used	Proportion of the drug
1	Meshashringi	Gymnema sylvestre R. Br.	Leaves	1 part
2	Vijayasara	Pterocarpus marsupium Roxb.	Heart wood	2 part
3	Jambu	Syzygium cumini Linn.	Seed	2 part
4	Haridra	Curcuma longa Linn.	Rhizome	1 part
5	Daruharidra	Berberis aristata DC.	Stem	1 part
6	Hareetaki	Terminalia chebula Retz.	Fruit	1 part
7	Vibhitaki	Terminalia belirica Roxb.	Fruit	
8	Amlaki	Emblica officinalis Gaertn.	Fruit	
9	Guduchi	Tinospora cordifolia willd.	Leaves	1 part
10	Tamala patra	Cinnamomum tamala (Buch,Ham)	Leaves	1 part

Table 3: Rasa panchaka of Madhumehari ghana vati

Sanskrit name	Rasa	guna	Veerya	Vipaka	Karma	Indication
Meshashringi	Kashaya, Tikta	Laghu, Ruksha	Ushna	Katu	Kaphavata shamaka	Madhumeha, Ikshumeha, Agnimandya,
Vijayasara	Kashaya, Tikta	Laghu, Ruksha	Ushna	Katu	Kaphapitta shamaka	Madhumeha, Prameha, Sthoulya
Jambu	Kashaya, madhura, amla	Laghu, Ruksha	Sita	Katu	Pitta shamaka	Madhumeha, Prameha, Sthoulya Raktapitta, Raktavikara.
Haridra	Katu, Tikta	Laghu, Ruksha	Ushna	Katu	Kapha pitta shamaka	Prameha, agnimandya
Daruharidra	Tikta, kashaya	Ruksha, Laghu	Ushna	Katu	Tridosha shamaka.	Vibandha, Prameha
Hareetaki	Pancharasa	Laghu, Ruksha	Ushna	Madhura	Tridoshashamaka	Prameha, Vatarakta, Agnimandya
Vibhitaki	Kashaya	Laghu, Ruksha	Ushna	Madhura	Tridoshashamaka	Prameha, Vatarakta, Agnimandya
Amlaki	Pancharasa (alavana) Amla (Pradhana)	Laghu, Ruksha, Sita	Sita	Madhura	Tridoshashamaka, especially Pittashamaka.	Daha, Daurbalya, meha,
Guduchi	Kashaya	Laghu, Ruksha	Ushna	Madhura	Tridoshashamaka	Vibandha, doubalya, rasayana, Prameha
Tamala patra	Madhura, Katu	Laghu, picchila, tikshna	Ushna	Katu	Kapha vata shamaka	Medoroga

Table 4: Ayurveda dietary plan

Timing Food Diary	Menu
Morning Drink B/w 6.30 am to 7 am (Any One)	1. Herbal Infused Drink (Lemon Added)-150 ml (1 Glass) 2. Ginger Lemon water -100 ml 3. Cinnamon water (lemon added)-100 ml 4. Fenugreek water-100ml 5. Herbal Juice-100 ml
8 am to 9 am Breakfast options (Any one)	1. Gram floor Dosa(Tomato Omlette)-1 in no + Herbal Chatni-2 tsf + Sambar-1 wati 2. Millet Dosa 1 to 2 in no/Millet Idli-2-3 in no + Herbal/ coconut Chatni-2 tsf + Sambar -1 wati 3. Millet Vegetable Upma-1 bowl/1 plate 4. Moong dosa-1 to 2 in no. + Herbal / coconut Chatni-2 tsf + Sambar-1 wati 5. Dhokla-2 pieces + Herbal chatni-2 tsf 6. Barley kichdi-1 bowl Breakfast with Herbal /Cardamom/Green Tea without sugar-1 cup
Mid-Morning Snack(Optional) 11.30 am to 12 pm	1. Medicated Buttermilk (Spiced with Ginger, Pepper, Rock salt and Jeera)- 1 Glass(150ml)
Lunch 1pm to 2 Pm	Mix Veg Salad (Raw-spiced with pepper powder and Rock Salt)-1 bowl + Unripe guava (1), Any citrus fruit(1),Berries(3 to 4) + Jowar/Bajra Roti-1 to 2 in number + Vegetable Sabji-1 wati + Boiled Pulses Sabzi/ Junka /moong Dal-4 th katori + Peanut/Methi/Flax Chatni-2 tsf + Dahi (Added with Rock salt or pink salt)



Mid-Evening Snack(optional) 4.30 pm to 5 pm (Option-Any one)	1. Almond-6 to 8 + Walnut-4 + Roasted /Soaked Peanuts-1 handful + Green Tea/Lemon tea without Sugar-1 handful
	1. Boiled black Chana chat-1 cup +Almond -6 +Walnut-3 + Green Tea/Lemon tea without Sugar-1 cup
	2. Boiled Peanut Chat or unsalted peanuts- 1 plate/1 handful + Green Tea/Lemon tea without Sugar-1 cup
	3. Mix sprout bhel (lemon and rock salt added)- 1 bowl + Green Tea/Lemon tea without Sugar-1 cup
Dinner (7 pm to 8 pm)	4. Moong usali/chana dal tikki/green gram vada/veg cutlet/karela fry/Moong dal tikki (any one)- 1 plate + Green Tea/Lemon tea without Sugar-1 cup
	1. Salad (spiced with lemon, pepper, rock salt)-1 bowl + Jowar /Bajra Roti-1 + Veg Sabzi-1 bowl + Millet Rice/millet pulav -1/2 wati + moong dal -1/2 katori + Herbal Raita-1 wati

Outcome measures

Subjective outcomes on *Prameha* as *purvaroop* and *laxana* assessment and diabetes quality of life measured on 0th, 30th, 60th and 90th day of intervention. Subjective outcomes were graded based on severity.

Anthropometric measures (weight, BMI) were assessed on 0th, 30th, 60th and 90th day of intervention.

Glycemic parameter assessment

HbA1C (in %) assessed on 0th and 90th day of intervention. Fasting blood glucose (FBS in mg/dl), Post prandial blood glucose (PPBS in mg/dl) were assessed on 0th, 30th, 60th and 90th day of intervention.

Lipid profile parameters assessed on 0th and 90th day of intervention.

Insulin resistance parameter: Fasting insulin (in mIU/l) and Homa IR (Homeostatic model for assessment for Insulin resistance) measured on 0th and 90th day.

Statistical methods

Baseline data including demographic data and patient profile between the groups was analyzed using χ^2 test. Result of the intervention at different time point between the groups was analyzed by Mann-Whitney U test. Wilcoxon matched pairs and Friedman's ANOVA test used to analyse within the group results at different time point.

Results

Demographic profile

Total 200 patients eligible for the study were randomised into SDT group and IAT group. In SDT group, among 100 subjects, total 8 subjects were dropped out and in IAT group among 100 subjects, 12 subjects were dropped due to various reasons. In this study, age wise distribution of subjects reveals, majority were above 61years (43%) followed by 51 to 60 years (34%) in SDP group and in IAP, maximum were between 41 to 50 years (41%) to above 61 years (35%). Gender wise, above 53% were male and 47% were females in SDT and 54% were male & 46% were female in IAT. Majority were from Hindu religion. Maximum subjects were graduated (37%) followed by primary school education (31%) in SDT and 33% graduates followed by 31% have primary education in IAT. Majority of subjects were married. Family history of diabetes found in 44% of participant's in SDT and 36% participants in IAT. Physical activity of subject's revealed moderate (50%) to sedentary (44%) activity

with 50 and 44% respectively in SDT and 61 to 34% in IAT (**Table no.5**). Personal history of subjects revealed majority had good bowel habit (i.e 72% in SDT and 71% in IAT), normal appetite (61% in SDT and 60% in IAT). Mixed dietary pattern is seen in both SDT (66%) and IAT (57%) group. Around 47% in SDT and 43% in IAT had *vata pitta prakrati* (constitution) followed by *pitta kapha prakrati* in 26% of participants in SDT and 31% participants in IAT. *Sara* (essence) of the subjects revealed majority had *medosara* (essence of adipose tissue) i.e. 90% in SDT and 88% in IAT group.

Subjective outcome

In this study, based on classical reference, assessment of clinical features of *prameha* was classified into two different parameters as *poorvaroop* (premonitory symptoms) and *Rupa* (symptoms). *Poorvaroop* assessment parameters included are *madhuryamasyata* (feeling sweetness in mouth), *angashaitilya* (flaccidity of muscles), *alasya* (indolence), *shitapriyatva* (desire for cold things), *angaganda* (body odour), *shramashwasa* (dysnoea on exertion), *swedadikyata* (perspiration) and *angasada* (physical fatigability).

Effect of intervention on *prameha poorva roopa* outcome showed significant difference favoring IAT group in *angashaitilya*, *alasya*, *shitapriyatva*, *angaganda*, *swedadikyata* and *angasada* features. In *angashaitilya*, significant difference was observed on 60th (p<0.05) and 90th (p<0.05) day of intervention. In *alasya* and *angaganda* changes were seen on 60th (p<0.05) and 90th (p<0.01) day of intervention. In *shramashwasa* and *angasada*, statistical significance was observed on 60th and 90th day of intervention (p<0.001). In *swedadikyata*, difference was observed on 60th (p<0.01) and 90th (p<0.001). No difference was observed between the group in *madhuryamasya* but significant changes shown within the SDT (p=0.001) and IAT (p<0.001) (**Table no.06**).

Impact of intervention on *Prameharoop* parameter showed significant difference towards IAT in *mutramadhurya*, *prabhutamutrata*, *pipasa* from 60th day of intervention with p value<0.001. In *Khsudadikyata*, between the group comparison showed that, significance in IAT was found on 60th (p<0.05) and 90th day (p<0.01). In *klama*, difference was observed between the group from 30th (p<0.05), 60th (p<0.001) day to 90th (p<0.001) day of intervention favoring IAT group. In *Purishabaddata*, between the group comparison showed that, IAT was significant on 90th day (p<0.05) (**Table no.07**).



Suketha Kumari et al., Efficacy of Integrated Ayurveda Treatment in Type 2 Diabetes mellitus with special reference to Prameha

Table 5: Comparison of Group A and Group B with demographic characteristics using chi-square test

Characteristics	Group SDT		Group IAT		Total		c ²	p-value
	n	%	n	%	n	%		
Age groups								
≤40yrs	7	7.00	17	17.00	24	12.00	9.0860	0.0280*
41-50yrs	16	16.00	25	25.00	41	20.50		
51-60yrs	34	34.00	23	23.00	57	28.50		
61yrs	43	43.00	35	35.00	78	39.00		
Gender								
Male	53	53.00	54	54.00	107	53.50	2.8200	0.4200
Female	47	47.00	46	46.00	93	46.50		
Religion								
Hindu	92	92.00	86	86.00	178	89.00	2.8200	0.4200
Muslim	3	3.00	3	3.00	6	3.00		
Christian	1	1.00	4	4.00	5	2.50		
Jain	4	4.00	7	7.00	11	5.50		
Education Status								
Illiterate	6	6.00	1	1.00	7	3.50	8.4900	0.1310
Primary School	31	31.00	31	31.00	62	31.00		
High School	21	21.00	22	22.00	43	21.50		
Diploma	0	0.00	3	3.00	3	1.50		
Graduate	37	37.00	33	33.00	70	35.00		
Post graduate	5	5.00	10	10.00	15	7.50		
Occupation								
Agriculture	6	6.00	5	5.00	11	5.50	1.9550	0.8550
Business	18	18.00	23	23.00	41	20.50		
Officer	29	29.00	22	22.00	51	25.50		
Home maker	32	32.00	35	35.00	67	33.50		
Teacher	5	5.00	4	4.00	9	4.50		
Labor	10	10.00	11	11.00	21	10.50		
Marital Status								
Married	94	94.00	83	83.00	177	88.50	8.1600	0.0430*
Unmarried	0	0.00	6	6.00	6	3.00		
Divorced	1	1.00	2	2.00	3	1.50		
Widowed	5	5.00	9	9.00	14	7.00		
Family history of T2DM								
Positive family history	44	44.00	36	36.00	80	40.00	1.3330	0.2480
Negative family history	56	56.00	64	64.00	120	60.00		
Physical activity								
Highly Active	6	6.00	5	5.00	11	5.50	2.4630	0.2920
Moderate	50	50.00	61	61.00	111	55.50		
Sedentary	44	44.00	34	34.00	78	39.00		

*p<0.05

Table 6: Effect on Pramehapurvarooopa variables using Mann-Whitney U test (between the groups) and Wilcoxon matched pairs (within the group). Expressed in mean and standard deviations (SD)

* p < 0.05, **p < 0.01, ***p < 0.001

Si.no	Parameter	Intervention	Baseline	30 th day	60 th day	90 th day	P value	BL-30 th	BL-60 th	BL-90 th
1	Madhuryamasya	SDT	0.5±0.9	0.5±0.8	0.5±8	0.5±8	0.55	<0.05*	<0.05*	<0.05*
		IAT	0.7±0.9	0.50±8	0.40±7	0.40±7		<0.001*	<0.001*	<0.001*
2	Angashaitilya	SDT	1.5±1.0	1.4±10	1.4±10	1.41±0	<0.05*	0.1614	0.1097	0.35
		IAT	1.3±1.0	1.2±1.0	1.1±1.0	1.0±0.9	<0.05*	0.0010*	0.0001*	0.0001*
3	Alasya	SDT	1.7±0.8	1.4±0.8	1.3±0.8	1.3±0.8	0.0012*	0.0001*	0.0001*	0.0001*
		IAT	1.9±0.8	1.4±0.8	1.0±0.8	0.9±0.8		0.0001*	0.0001*	0.0001*
4	Shitapriyatwa	SDT	1.1±0.9	1.0±0.9	0.9±0.9	0.9±0.9	0.0011*	0.0117*	0.0003*	0.0002*
		IAT	0.9±1.0	0.7±0.8	0.5±0.6	0.4±0.6		0.0010*	0.0001*	0.0001*
5	Angagandha	SDT	1.1±0.9	0.9±0.8	0.8±0.8	0.7±0.8	0.0059*	0.0001*	0.0001*	0.0001*
		IAT	1.10.9	0.80.8	0.50.7	0.40.6		0.0001*	0.0001*	0.0001*



6	Shramashwasa	SDT	1.4±0.9	1.2±0.8	1.1±0.9	1.1±0.9	0.0001*	0.0022*	0.0001*	0.0001*
		IAT	1.3±0.9	1.0±0.8	0.5±0.6	0.5±0.6		0.0001*	0.0001*	0.0001*
7	Swedadikyata	SDT	1.5±0.8	1.3±0.8	1.1±0.8	1.1±0.8	0.0001*	0.0001*	0.0001*	0.0001*
		IAT	1.6±0.8	1.3±0.9	0.7±0.8	0.6±0.8		0.0001*	0.0001*	0.0001*
8	Angasaada	SDT	1.7±0.8	1.5±0.8	1.3±0.9	1.3±0.8	0.0001*	0.0004*	0.0001*	0.0001*
		IAT	1.8±0.7	1.4±0.8	0.9±0.8	0.8±0.8		0.0001*	0.0001*	0.0001*

Table 7: Effect on *Prameha roopa* variables using Mann-Whitney U test (between the groups) and Wilcoxon matched pairs (within the group). Expressed in mean and standard deviations (SD)

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Si.no	Parameter	Intervention	Baseline	30 th day	60 th day	90 th day	P value	BL-30 th	BL-60 th	BL-90 th
1	Mutramadhurya	SDT	1.8±2.0	1.6±2.0	1.4±1.0	1.3±1.0	0.0001*	0.0001*	0.0001*	0.0001*
		IAT	2.0±2.0	1.4±1.0	0.8±1.0	0.7±0		0.0001*	0.0001*	0.0001*
2	Prabhuta Mutrata	SDT	1.6±1.0	1.3±1.0	1.2±1.0	1.1±1.0	0.0001*	0.0001*	0.0001*	0.0001*
		IAT	1.6±2.0	1.2±1.0	0.6±1.0	0.5±0.0		0.0001*	0.0001*	0.0001*
3	Pipasaadhikya	SDT	1.7±2.0	1.4±1.0	1.3±1.0	1.2±1.0	0.0001*	0.0001*	0.0001*	0.0001*
		IAT	1.8±2.0	1.3±1.0	0.8±1.0	0.6±0.0		0.0001*	0.0001*	0.0001*
4	Kshudhaadhikya	SDT	1.7±2.0	1.5±2.0	1.3±1.0	1.3±1.0	0.0002*	0.0001*	0.0001*	0.0001*
		IAT	1.9±2.0	1.6±2.0	1.0±1.0	0.8±1.0		0.0001*	0.0001*	0.0001*
5	Klama	SDT	1.5±1.0	1.4±1.0	1.3±1.0	1.2±1.0	0.0001*	0.0117*	0.0001*	0.0001*
		IAT	1.4±1.0	1.1±1.0	0.8±1.0	0.7±1.0		0.0001*	0.0001*	0.0001*
6	Purishabaddhata	SDT	0.6±0.0	0.5±0.0	0.4±0.0	0.3±0.0	0.0252*	0.0051*	0.0002*	0.0001*
		IAT	0.6±0.0	0.4±0.0	0.2±0.0	0.1±0.0		0.0001*	0.0001*	0.0001*

Glycaemic outcome

The impact of the intervention on HbA1c revealed a significant difference ($p < 0.001$), with the mean percentage change in IAT (16.58%) being higher than that of SDT (4.82%), favouring the IAT group. In FBS parameter there is a significant difference between the group ($p = 0.001$). The IAT group shown changes from 30th ($p = 0.001$), 60th ($p < 0.001$), and 90th ($p < 0.001$) day of the intervention in group analysis. In SDT group, changes were evident on the 90th ($p < 0.001$) day of the intervention. In FBS parameter, there is a significant difference between the groups ($p = 0.001$). Individual group analysis revealed that there were changes in the IAT group on the 30th ($p = 0.001$), 60th ($p < 0.001$), and 90th ($p < 0.001$) day of the intervention, where as in SDT group changes visible on 90th day of intervention ($p < 0.001$). The result of intervention on PPBS showed significant difference between the group ($p < 0.001$) which is favouring to IAT group had shown changes on 30th, 60th, and 90th day of intervention ($p < 0.001$)

Lipid profile outcome

In lipid profile parameter both the group shown significant changes in Total cholesterol ($p = 0.007$ in SDT & $p = 0.001$ in IAT), very low density lipoprotein ($p = 0.001$ in SDT and $p < 0.001$ in IAT group) and serum triglycerides ($P < 0.001$ in both SDT and IDT group). High density lipoprotein and low density lipoprotein had not shown any results in this study.

Anthropometric measure outcome

From the baseline to the 30th, 60th, and 90th day of the intervention, in weight and BMI, there was a substantial decrease in both SDT and IAT group ($P < 0.001$). Mean changes in weight was from 69.30 kg's to

68.67 kg's in SDT and 71.43 to 68.39 kg's in IAT group.

Insulin resistance outcome

Result of intervention on serum insulin showed significant change between the group ($p < 0.05$), with the IAT group had superior improvement ($p < 0.001$). Intervention outcome on HomaIR showed significant difference ($p = 0.001$). Within the group, IAT had shown more improvement ($p < 0.001$).

Diabetes quality of life

Diabetes quality of life domains are satisfaction, impact and concern (Social and diabetes specific). Results on quality of life with above domains showed that group IAT had good improvement ($p < 0.001$) at all-time points of the study i.e on 30th, 60th and 90th day of the study.

Discussion

This study revealed that, Integrated Ayurveda treatment (IAT) showed beneficial outcome compared to Standard Diabetic treatment (SDT) in maximum parameters of *prameha purvarupa* except in *madhuryamasya*. In *Prameha rupa*, all the parameters showed statistical significance favouring to IAT group. Ayurveda treatment group showed benefits in HbA1c, FBS, PPBS and Insulin resistance parameters. Both the group had shown results in weight, BMI and few components of lipid profile (i.e Total cholesterol, VLDL and Triglycerides).

In this study, the majority of subjects were over 41 years old; however, currently, it is observed that type 2 diabetes can develop at a young age, usually driven by insulin resistance due to obesity and ethnicity. Religion-wise, the distribution of subjects revealed that Hindu



Suketha Kumari et al., Efficacy of Integrated Ayurveda Treatment in Type 2 Diabetes mellitus with special reference to Prameha

subjects were predominant in both groups. This may be due to the maximum population of Hindu subjects in the study area. Subjects in the graduated and primary school categories of educational status were found which shows that prevalence is not strongly related to the educational status of the subjects. Different occupation distributions were found, so no conclusion could be drawn about the prevalence of the disease. Subjects with a sedentary lifestyle to moderate physical activity were found, revealing that lifestyle has a stronger role to play in disease manifestation.

Ayurveda herbs are extensively used for different health conditions and general welfare. MGV has ten herbs i.e. *Meshashringi* (*Gymnema Sylvestre* Retz.), *Jambu* (*Syzygium cumini* L.), *Triphala* (a blend of *Embllica officinalis* Gaertn, *Terminalia chebula* Retz, *Terminalia belirica* Roxb.), *Vijayasara* (*Pterocarpus marsupium* Roxb.), *Haridra* (*Curcuma longa* Linn), *Guduchi* (*Tinospora cordifolia* Willd.), *Tamala patra* (*Cinnamomum tamala* (Buch,Ham) and *Daruharidra* (*Berberis aristata* DC). All the herbs have *pramehaghna* property hence showed significant benefits in glycaemic outcomes. Drugs such as *Jambu*, *Asana*, *Haridra* are having potent anti-diabetic activity, also they are having *pitta* mitigating property, hence might helped in symptoms of *Pipasadikyata*, *kshudadikyata* etc. An open label clinical trial conducted in 4 centres of India to see the efficacy of *vijayasara* (*Pterocarpus marsupium* Roxb.) in non-insulin dependent diabetes mellitus had shown reduction in glycaemic parameters and lipid changes (18). The research done on the extract from *syzygium cumini* demonstrates the existence of phenolic compounds with anti-oxidant and anti-glycation properties that can mediate their anti-diabetic benefits (12). A meta-analysis of various studies have shown the beneficial effects of curcumin and its preparation in Asian pre-diabetes and T2DM patients by reducing HbA1c (19). *Meshashringi*, *Tamala patra*, *Daruharidra* have *kapha medohara* and *lekhana* (scrapping) action might help in reversing the pathogenesis (9, 10). A clinical trial on T2DM, administered with 500 mg of *Meshashringi* (*Gymnema sylvestre* R. Br.) along with diet for a period of 90 days shown beneficial effect in polyphagia and other symptoms (20). Patients with T2DM who received 1 mg of *daruharidra* fruit extract showed results in blood glucose regulation (21). An oral administration of an ethanolic extract of *Cinnamomum tamala* (200 mg/kg body weight) for 40 days resulted in a significant reduction in blood glucose levels and the maintenance of body weight and lipid profile parameters close to normal in diabetes induced experimental animals. *Guduchi* and *Triphala* have added *rasayana* advantages (22, 23) in addition to the aforementioned ones, which may have an impact on *Angashitilya*, *Sada*, and *Klama*.

The Ayurvedic diet planned here consists of millet-based meals, plant-based food treated with herbs, time-restricted eating with 2 to 3 meal method, and avoids processed and junk food. Time restricted eating have benefits in body weight and fat mass (24), improves glucose tolerance hence showed results in this

study. The *Ayurvedic* concept of dietary recommendations for lifestyle diseases is *guru cha aatarpana*, i.e., food that is heavy and rich in nutrients without causing over nourishment (25) and avoids excess fat storage, like foods made of millet. This theory helps to balance the metabolism and prevent overeating, which is why this study found the effective outcomes. This diet contained majority of plant-based food. A meta-analysis of six randomised controlled trials (N = 255) found that plant diets were associated with a 0.4% larger drop in glycated haemoglobin (HbA1c) than other suggested dietary patterns for diabetic people (26). Review on benefits of *yogasana*'s reveal that, ten minutes of yoga intervention combined with standard medical care for 10 minutes helped to improve metabolic health significantly. Combined effect of *Madhumeha ghana vati* with *pathyahara* and integration of yoga showed benefits in type 2 diabetes without causing any adverse events.

Conclusion

This study evaluated efficacy of integrated Ayurveda treatment which consist of an Ayurveda poly herbal formulation *Madhumehari ghana vati* along with diet and *yoga* showed beneficial effect in majority of parameters of *Prameha poorvaroopa* and *roopa* in a duration of 90 days. The efficacy result was also noticed in diabetes quality of life parameters. Study showed benefits in glycaemic outcomes compared to standard control group. Comparable results were observed in lipid profile and anthropometric measures. Study conducted with adequate sample size is strength of this study. Long term intervention is needed to see the better results. No any adverse events seen in this study.

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Ethics statement

Authors certify that appropriate patient consent was taken

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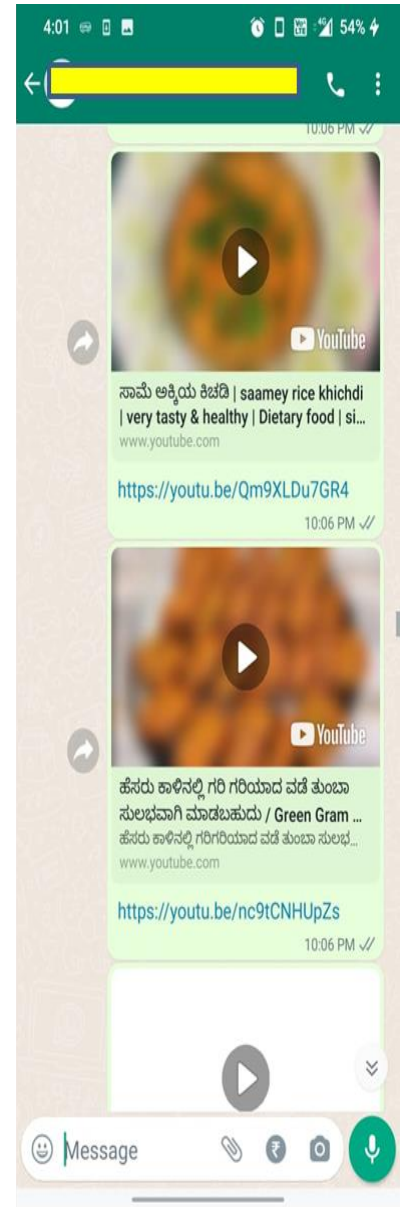
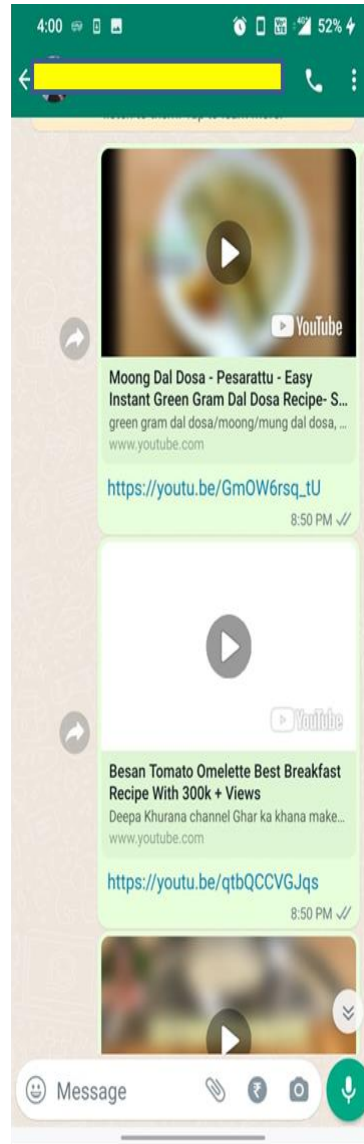


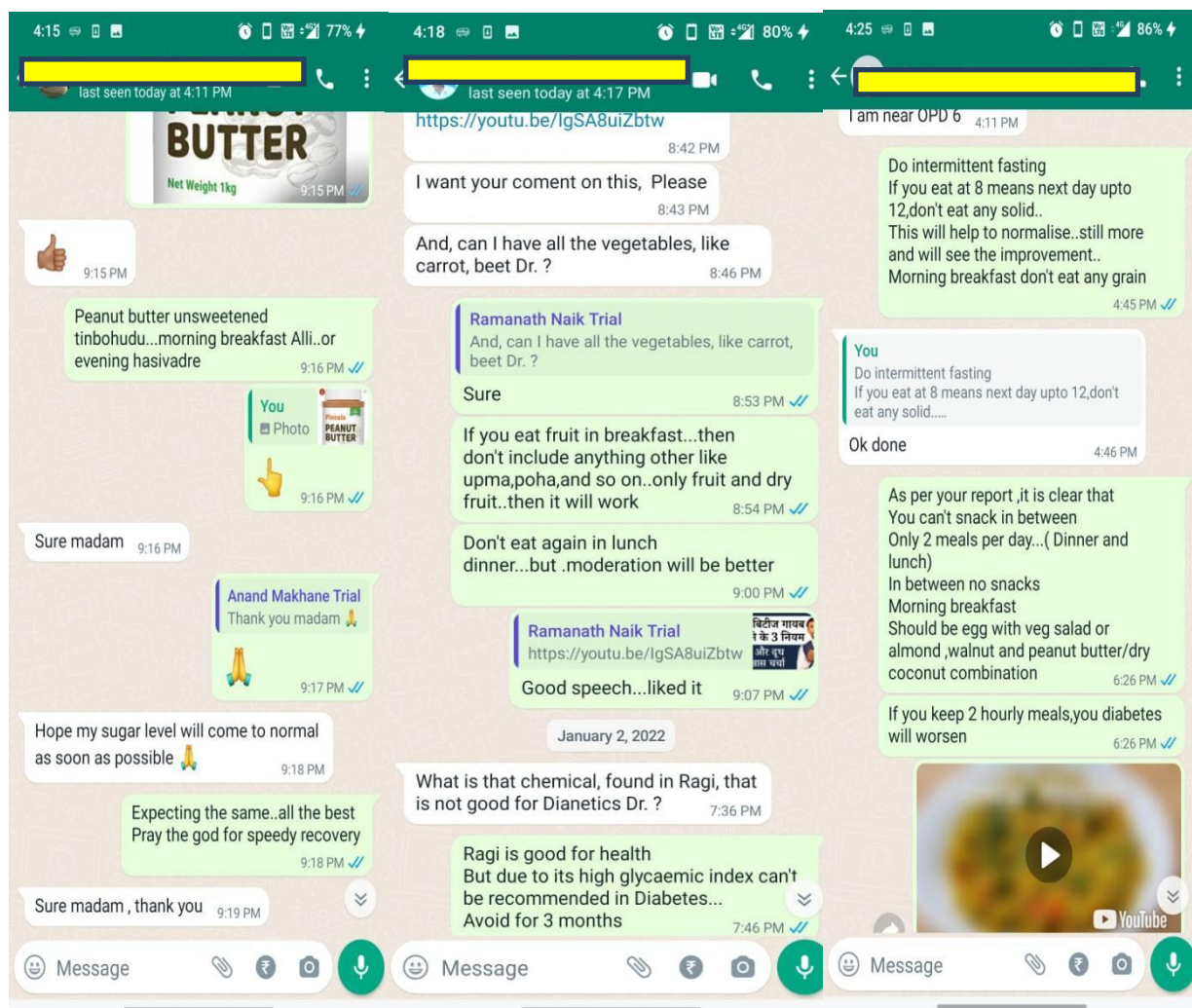
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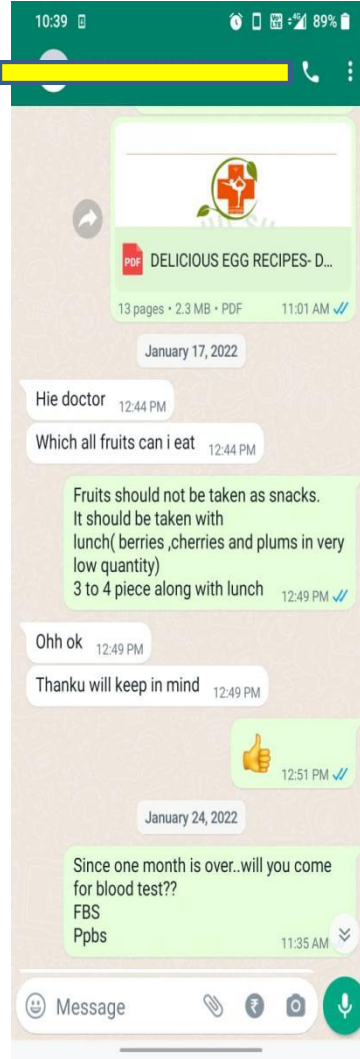
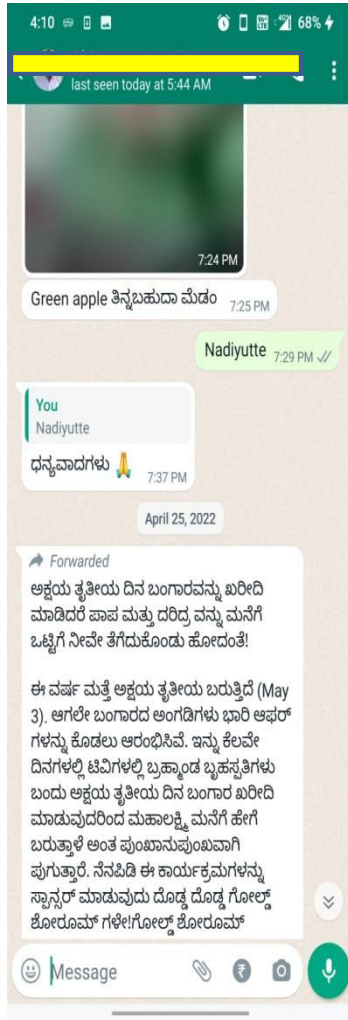
ANNEXURE 6: DIETARY AND LIFESTYLE ADHERENCE MONITORING AND SOCIAL SUPPORT

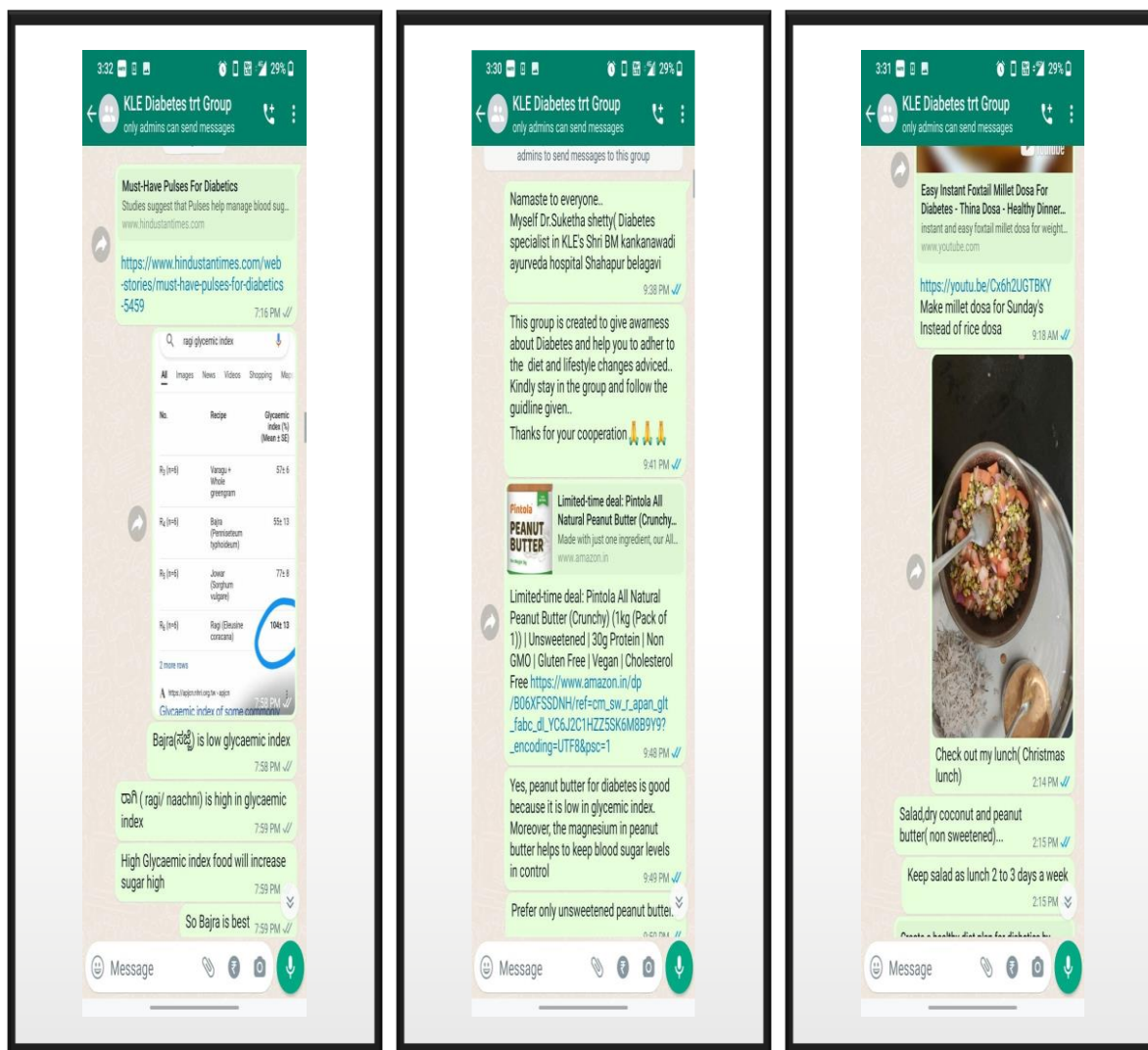














7/16/2024



8th Half Yearly presentation Dr. Suketha



152



7/16/2024



8th Half Yearly presentation Dr. Suketha



153



Patient Name: Vajrakumara Daddannavar / Subject No: 3.

DIET ADHERENCE DAIRY

DAY	Morning Drink	Breakfast	Mid-morning Snacks	Lunch	Evening snacks	Dinner
1	✓	✓	✓	✓	✓	✓
2	✓	✓	✓	✓	✓	✓
3	✓	✓	✓	✓	✓	✓
4	✓	✓	✓	✓	✓	✓
5	✓	✓	✓	✓	✓	✓
6	✓	✓	✓	✓	✓	✓
7	✓	✓	✓	✓	✓	✓
8	✓	✓	✓	✓	✓	✓
9	✓	✓	✓	✓	✓	✓
10	✓	✓	✓	✓	✓	✓
11	✓	✓	✓	✓	✓	✓
12	✓	✓	✓	✓	✓	✓
13	✓	✓	✓	✓	✓	✓
14	✓	✓	✓	✓	✓	✓
15	✓	✓	✓	✓	✓	✓
16	✓	✓	✓	✓	✓	✓
17	✓	✓	✓	✓	✓	✓
18	✓	✓	✓	✓	✓	✓
19	✓	✓	✓	✓	✓	✓
20	✓	✓	✓	✓	✓	✓
21	✓	✓	✓	✓	✓	✓
22	✓	✓	✓	✓	✓	✓
23	✓	✓	✓	✓	✓	✓
24	✓	✓	✓	✓	✓	✓
25	✓	✓	✓	✓	✓	✓
26	✓	✓	✓	✓	✓	✓
27	✓	✓	✓	✓	✓	✓
28	✓	✓	✓	✓	✓	✓
29	✓	✓	✓	✓	✓	✓
30	✓	✓	✓	✓	✓	✓
31	✓	✓	✓	✓	✓	✓
32	✓	✓	✓	✓	✓	✓
33	✓	✓	✓	✓	✓	✓
34	✓	✓	✓	✓	✓	✓
35	✓	✓	✓	✓	✓	✓
36	✓	✓	✓	✓	✓	✓
37	✓	✓	✓	✓	✓	✓
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43	✓	✓	✓	✓	✓	✓
44	✓	✓	✓	✓	✓	✓
45	✓	✓	✓	✓	✓	✓

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46	✓	✓	✓	✓	✓	✓
47	✓	✓	✓	✓	✓	✓
48	✓	✓	✓	✓	✓	✓
49	✓	✓	✓	✓	✓	✓
50	✓	✓	✓	✓	✓	✓
51	✓	✓	✓	✓	✓	✓
52	✓	✓	✓	✓	✓	✓
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84	✓	✓	✓	✓	✓	✓
85	✓	✓	✓	✓	✓	✓
86	✓	✓	✓	✓	✓	✓
87	✓	✓	✓	✓	✓	✓
88	✓	✓	✓	✓	✓	✓
89	✓	✓	✓	✓	✓	✓
90	✓	✓	✓	✓	✓	✓

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Diet adherence fraction: 82%