IAMJ

INTERNATIONAL
AYURVEDIC
MEDICAL JOURNAL

Research Article | ISSN: 2320 5091 | Impact Factor: 5.344

AN OPEN LABELLED, RANDOMIZED, CONTROLLED, PROOF OF CONCEPT, COMPARATIVE STUDY TO ANALYZING THE EFFECT OF POLYHERBAL FORMULATIONS VIZ. MADHUNIL (DIABHAR), MADHUYOG (SUGARID) & DIABETOX TREATMENT PLAN FOR THE TREATMENT OF MADHUMEH – DIABETES TYPE 2

Smita Naram[1], Hemang Parekh[2], Deepak Mahajan[3], Ronak Naik[4]

[1]Founder, Chairman and Managing Director Ayushakti Ayurveda Pvt Ltd, Bhadrannagar crossroad, Malad, Mumbai-64, Maharashtra, India
[2]Consulting Ayurveda Physician Ayushakti Ayurveda Pvt Ltd, Bhadran nagar crossroad, Malad, Mumbai-64, Maharashtra, India
[3]Consulting Ayurveda Physician Ayushakti Ayurveda Pvt Ltd, Bhadran nagar crossroad, Malad, Mumbai-64, Maharashtra, India
[4]Consulting Ayurveda Physician Ayushakti Ayurveda Pvt Ltd, Bhadran nagar crossroad, Malad, Mumbai-64, Maharashtra, India

Corresponding Author: drdeepakm@ayushakti.com

https://doi.org/10.46607/iamj1308112020

(Published online: November 2020)

Article Received: 31/10/2020 - **Peer Reviewed:** 06/11/2020 - **Accepted for Publication:** 09/11/2020

ABSTRACT

Background-*Madhumeh* – Diabetes Type 2 has a potential to cause a worldwide healthcare crisis hence finally being recognised as a global epidemic. *Madhumeh* – Diabetes Type 2 patients initially respond to all the measures including Oral Hypoglycaemic Agents, but some of the patients develop resistance to the drugs right from the beginning or in due course .To help society in this regard, there is an option for a Holistic treatment, which helps to balance the sugar levels without any side effects. Diabetes Type 2 matches with *Madhumeh* in Ayurveda, which is

one of 20 types of *Prameh. Virechan* (detoxification) is one of the most Invigorating, Energizing and rejuvenating treatments that helps in *Madhumeh*. **Material and Methods**- Patients were randomly selected from the OPD of Ayushakti Ayurved Pvt Ltd, Malad, with classical signs and symptoms of *Madhumeh*. They received a Blood Test, Diabetox - *Virechan karma*, selected Herbal formulations and an adjusted Diet. This present study shows that when both tablets *Madhunil (Diabhar)* and *Madhuyog (Sugarid)* were administered in newly diagnosed *Madhumeh* – Diabetes Type 2 patients. **Results**-We were able to decrease the hyperglycaemic and hyperlipidaemic conditions significantly without any toxic - or side effects. We were also able to minimise the dose of OHA. When these polyherbal formulations were used alongside Diabetox - *Virechan* program (detoxification), we were able to reduce the complications. **Conclusion-**The above clinical trial reports the hypoglycaemic and hypolipidaemic effect of the polyherbal combinations *Madhunil (Diabhar)* and *Madhuyog (Sugarid)*.

Keywords- Diabetes Type-2, Madhumeh, Diabetox, polyherbal, Virechan, Madhunil (Diabhar), Madhuyog (Sugarid).

INTRODUCTION

Diabetes has a potential to cause a worldwide healthcare crisis hence finally being recognised as a global epidemic. In 1997 the World Health Organisation reported that by the year 2000 we would see 153.9 million diabetics worldwide, and by 2025 this could increase to 299.1 million. In 2030 this figure can further increase to 552 million people with diabetes worldwide[1]. In Diabetes, the pancreas either produces less insulin or the body cells are unable to respond to the insulin produced[2]. Through timely diagnosis and well managed medicines, along with lifestyle and diet modifications, we are able to control diabetes. *Madhumeh* – Diabetes Type 2 patients initially respond to all the measures including Oral Hypoglycaemic Agents, but some of the patients develop resistance to the drugs right from the beginning or in due course. Poor diet compliance and progressively worsening of Beta cell function are the major causes of OHA failure[3]. The available treatment can prevent some devastating complications but does usually not restore the normal glycaemia or eliminate all the adverse consequences. Since current methods of treating Diabetes remain inadequate, prevention is preferable [4.] Patients search for alternative therapies to tackle Diabetes type 2. If we search our Indian history of treating various diseases, we get the answers by means for traditional herbs. There is a variety of traditional herbs and herbal combinations available in the ancient manuscripts and Samhitas of Ayurveda. The side effects of regular medicines also increase the large number of people with serious diabetic complications.

To help society in this regard, there is an option for a Holistic treatment, which helps to balance the sugar levels without any side effects. The Holistic Treatment plan improves the Pancreas function by increasing the insulin secretion or by reducing the intestinal absorption of glucose. Aacharya Charaka and Aacharya Sushruta have mentioned 20 varieties of *Prameh* under *Vata, Pitta* and *Kapha* categories. In the progression of diabetes, at the initial stage of *Prameh, Kapha* (*Dosha*) is increasing at a high level (*Kaphavrddhi)* later decreasing to *Kaphakshaya.* Diabetes Type 2 matches with *Madhumeh* in Ayurveda, which is one of 20 types of *Prameh*. To date, over 400 plants are reported in folk medicine for treatment of Diabetes Type 2, although only a small number of these have received scientific and medical evaluation to assess their efficacy. The Hypoglycaemic effect of some herbal extracts has been confirmed in human and animal models of diabetes type 2.

Diabetox - *Virechan* is one of the most Invigorating, Energizing and rejuvenating treatments that helps in Diabetes type 2.The first stage consists of the removal of intestinal mucus *(Aam*) by taking a very light diet plus *Deepan* (Appetizing) and *Pachan* (Digestive) herbs like *Supachak* and *Hingastak*, and undergoing preparatory treatments that are individually prescribed.

Thereafter *Snehan* (internal and External Oleation) and *Swedan* (Special Steam treatment) are administered to loosen *Aam* (Toxins) and excess Doshas in the deeper body tissues. Once loosened, these impurities gradually they return to the digestive tract via different body channels from which they can be easily removed with the Diabetox Process. To get the full benefit from the treatment, it is extremely important to take as much rest as possible and not engage in travelling or any other strenuous activities.

Aim and Objective-

1 Primary objective:

- To assess the effectiveness of Ayurvedic polyherbal formulations viz. *Madhunil (Diabhar)* tablets and *Madhuyog (Sugarid)* tablets and the treatment plan when given as add on therapy in the management of *Madhumeh* – Diabetes Type 2, with regards to Blood sugar levels.
- To assess the effectiveness of Ayurvedic treatment plan – Diabetox (*Virechan*)

2 Secondary Objectives:

- To assess the change in the various biochemical markers between the study groups at the end of the treatment, along with the changes in symptoms described in Ayurvedic texts thousand years back.
- To assess the clinical safety of Ayurveda treatment packages.

Material and Methods-This particular study includes patients recently diagnosed with *Madhumeh* – Diabetes Type 2, Blood Tests, Diabetox - *Virechan* program (Detoxification), selected Herbal formulations and Diet. **Ethical considerations-**The study was conducted after obtaining permission from the Scientific Research committee at Ayushakti Ayurveda Pvt Ltd, Bhadran Nagar crossroad, Malad, Mumbai, Maharashtra, India. Patients were randomly selected from the OPD of Ayushakti Ayurveda Pvt Ltd, Malad with classical signs and symptoms of *Madhumeh*, irrespective of sex, religion, caste, occupation etc. Recently diagnosed cases of *Madhumeh* – Diabetes Type 2 were selected for the study after confirmation by the results of their blood sugar levels tests. Patients were recruited into the study following written informed consent.

Inclusion Criteria:

1. Patients of both genders between the age group of 30-75 years (both years inclusive)
2. Known case of *Madhumeh* – Diabetes Type 2 since the last 2 years and receiving anti-diabetic medications.
3. On stable treatment regimen with either metformin (1500 mg per day) and/or other OHAs (refer Annexure 1) for at least three months.
4. Fasting blood sugar level above 140 mg/dl
5. Post-prandial blood sugar level above 180 mg/dl
6. Ready to abide by trial procedures and to give informed consent

Exclusion Criteria:

1. Type 1 diabetes
2. Patients with severe hyperglycaemia
3. Patients in whom Virechan is contraindicated
4. Patients with impaired liver or kidney function
5. Clinically significant active cardiovascular disease and uncontrolledtreated/untreated hypertension
6. Diabetes due to an endocrinopathy like Acromegaly, Cushing's syndrome, Hyperthyroidism
7. Recurrent major episodes of hypoglycaemia or hypoglycaemic unawareness
8. Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)
9. Alcohol and/ or drugs abuse
10. Pregnant and lactating women
11. History of hypersensitivity to any of the trial drugs or their ingredients.

Plan of Study-

The selected patients were categorized randomly into three following groups:

1. Group- I- 30 patients diagnosed with *Madhumeh* – Diabetes Type 2 received their ongoing Anti diabetic medicines (Control group).
2. Group II- 30 patients diagnosed with *Madhumeh* – Diabetes Type 2 received medication *Madhunil (Diabhar)* tablet 640 mg and *Madhuyog (Sugarid)* tablet 730 mg. These medicines are to be taken with water and food in the dose of 2 tablets twice

a day. Patients also continued to consume their ongoing anti-diabetic treatment. Patients were asked to follow up at monthly intervals for medical check-up and assessment of blood sugar levels.

3. Group III- 30 patients diagnosed with *Madhumeh* – Diabetes Type 2 received the Diabetox treatment plan: *Virechan* procedure (Detoxification) alongside *Madhunil (Diabhar)* and *Madhuyog (Sugarid)* tablets (as described in Group II).

Study duration- Each participant was part of a 6 months study. The entire study duration was 12 months.

Intervention-

- *Mahanarayan* oil for external *Snehan* (oleation)
- *Mahatriphalaghrut* (ghee) for internal *Snehan* (oleation)
- *Virechan plus* tablet for *Virechan* (Purgation)
- *Madhunil (Diabhar)* tablet 640 mg
- *Madhuyog (Sugarid)* tablet 730 mg

Herbal Remedies-

All the drugs were purchased from Ayushakti Ayurveda Pvt Ltd, Plot number 78, Stice, Musalgaon, Sinnar, Nashik-422112

Assessment Criteria-

The results were assessed with a scale developed by Ayushakti Ayurveda Pvt Ltd, It probes clinically important symptoms in the areas of physiological functions in patients with *Madhumeh* – Diabetes Type 2.The index consists of 5 questions depending on the 5 symptoms of *Madhumeh* described in Ayurvedic texts. Individual scale question responses are assigned a score between 0 (none) to 3/4 (Extreme). A total assessment of the therapies was done on the basis of relief in the main signs and symptoms of the disease. After completion of study, the results were assessed by following criteria-

1. Improvement in the signs and symptoms of *Madhumeh* – Diabetes Type 2 on the basis of symptoms score.
2. Fasting blood sugar level (FBS) and Post prandial blood sugar levels (PPBS) and HbA1c, Lipid profile.

Statistical analysis-

Mean score (X), Standard deviation (SD), Standard error (SE) and a paired TDS test were carried out at the level of 0.05, 0.01 and 0.001 of p level. After this the results were interpreted as follows:

$P > 0.05$ = insignificant

$P < 0.05$ = significant

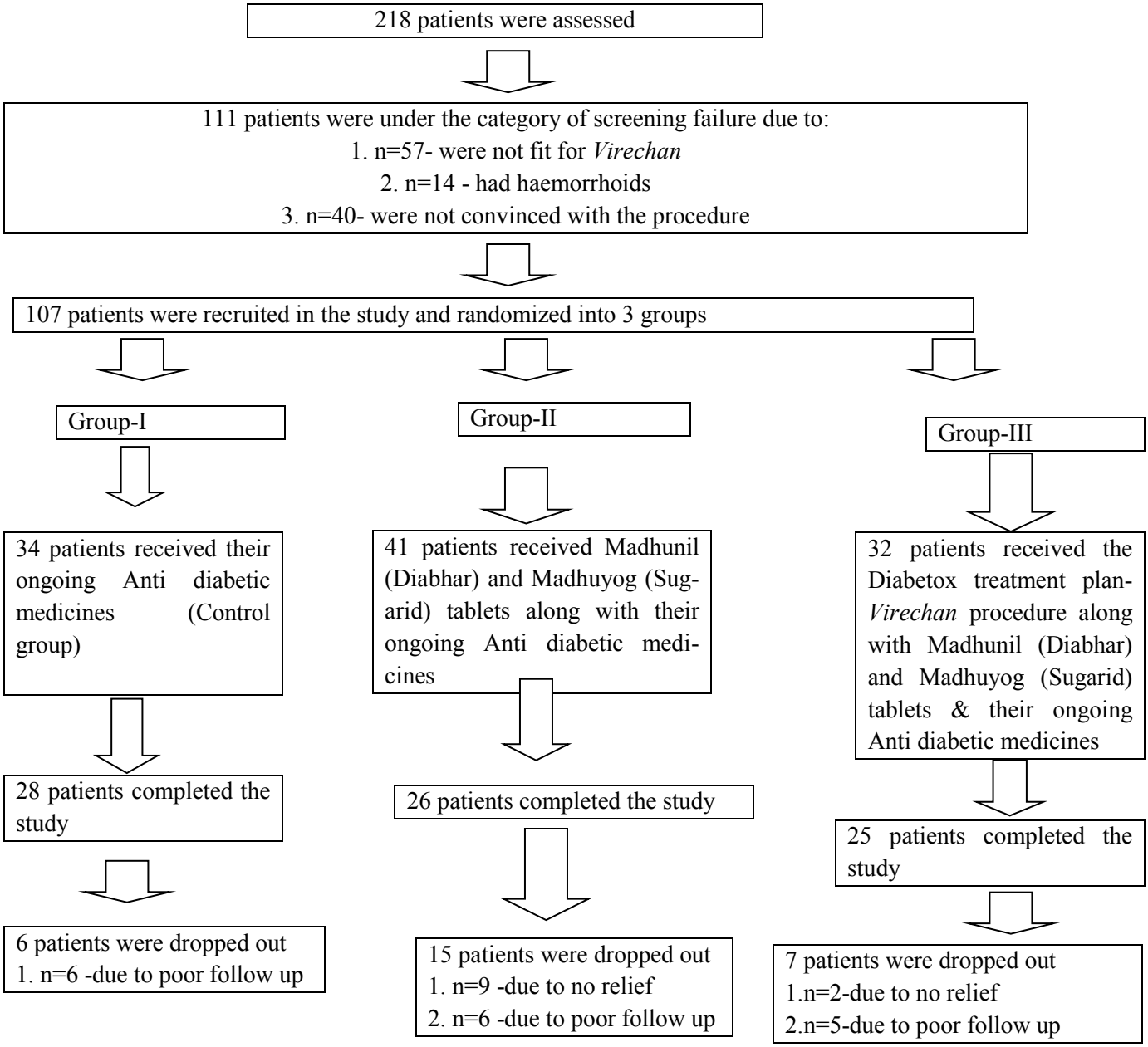
$P < 0.01$ = significant result

$P < 0.001$ = highly significant result

Results-

The study flow chart is shown in Figure 1.

Figure 1: Study flow chart



Effect on blood sugar level-

This distribution as shown in figure 2 demonstrate that there is an improvement in blood sugar levels in all the groups; though significant improvement was observed in Group-III as compared to Group-I (Control group) and Group-II. The result was statistically significant at day 180 and is shown in Figure 2 & 3.

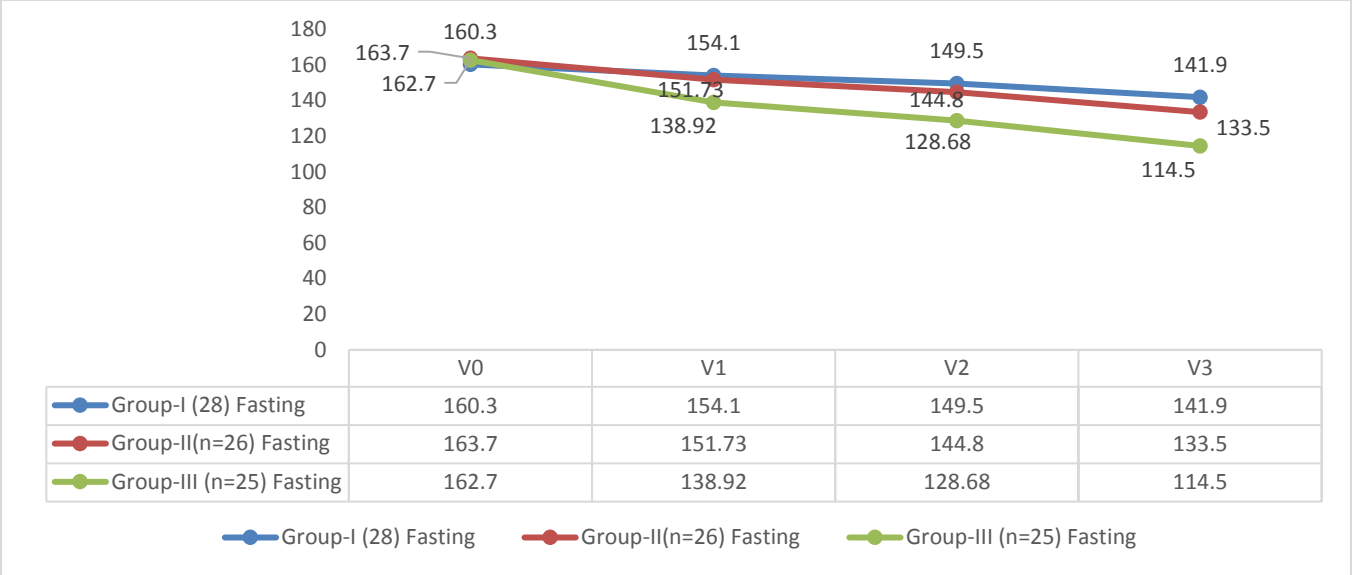


Figure 2: Effect of study medication on Fasting blood sugar level-

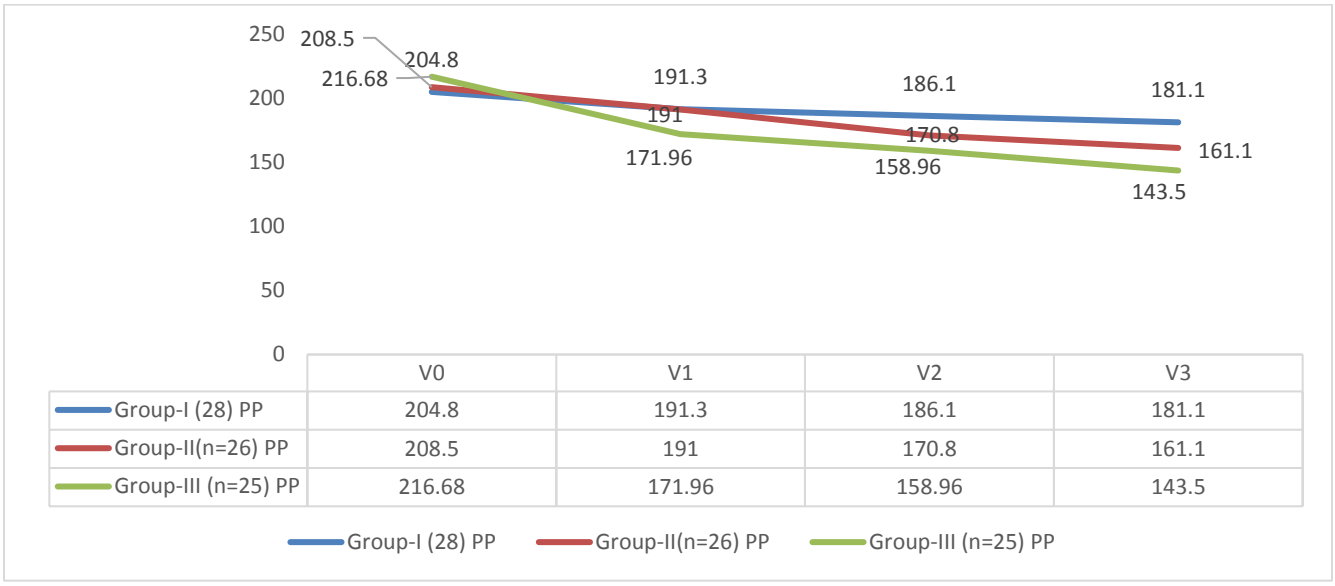


Figure3: Effect of study medication on Post prandial blood sugar level-
(<0.0001 in G-I FBS, 0.006 in GI PP, <0.0001 in G-II FBS, <0.0001 in G-II PP,<0.0001 in G-III FBS, <0.0001 in G-III PP by Kruskal-Wallis test (Nonparametric ANOVA) as compared to control group)

Effect of on Glycated haemoglobin A1c level-

All three groups showed improvement in Glycated haemoglobin A1c level.

A statistically significant difference was observed in Group-III at the end of 180 days and is shown in figure 4.

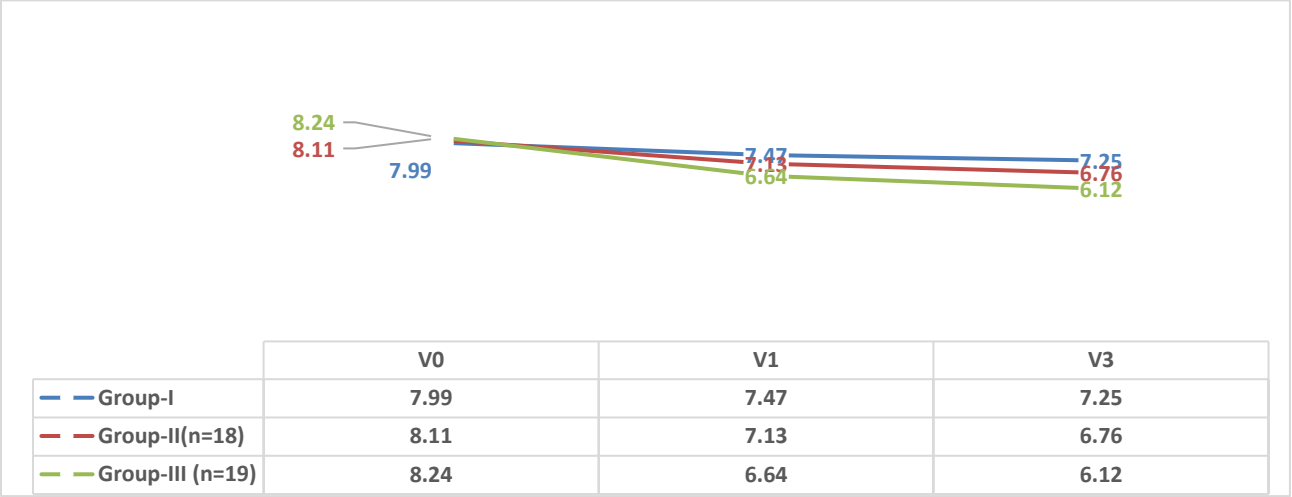


Figure 4: Effect of study medication on Glycated haemoglobin A1c level

Effect on Ayurvedic symptoms score-

The Ayurvedic *Madhumeh* symptoms were assessed with regards to the five *Madhumeh* symptoms using the visual analogue scale (VAS). A statistically significant improvement was observed in the following five symptoms, as compared to the baseline scores at days 30, 90 and 180 in both study treatment groups i.e. Group-II and

Group-III. The results are shown in table 1.

***Prabhut Mutrata* (Polyuria)**								
	V0	V1	V2	V3	% Diff	SD	SE	P' Test
Group-1 (n=23)	1.92	1.72	1.68	1.6	16.66667	0.5568	0.1114	0.0084
Group-II(n=18)	2	1.388889	0.777778	0.722222	63.88889	0.6691	0.1577	<0.0001
Group-III (n=19)	1.894737	0.947368	0.368421	0.368421	80.55556	0.7723	0.1772	<0.0001
***Avil Mutrata* (Turbid Urine)**								
	V0	V1	V2	V3	% Diff	SD	SE	P' Test
Group-I (n=19)	2.631579	2.210526	2.052632	1.842105	30	0.7873	0.1806	0.0004
Group-II(n=12)	2.5	1.666667	0.833333	0.916667	63.33333	0.6686	0.193	<0.0001
Group-III(n=15)	2.666667	1.533333	0.466667	0.466667	82.5	0.6761	0.1746	<0.0001
***Kshudhadhikya* (Polyphagia)**								
	V0	V1	V2	V3	% Diff	SD	SE	P' Test
Group-I (n=19)	2	1.789474	1.789474	1.578947	21.05263	0.607	0.1393	0.0073
Group-II(n=15)	2.066667	1.266667	0.6	0.666667	67.74194	0.5071	0.1309	<0.0001
Group-III (n=14)	2.21429	1.28571	0.5	0.57143	74.19355	0.6333	0.1693	<0.0001
***Trushnadhikya* (Polydipsia)**								
	V0	V1	V2	V3	% Diff	SD	SE	P' Test
Group-I(n=22)	1.789474	1.315789	1.263158	1.105263	38.23529	0.6463	0.1378	<0.0001
Group-II(n=17)	1.941176	1	0.470588	0.470588	75.75758	0.7174	0.174	<0.0001
Group-III (n=14)	2.357143	1.214286	0.357143	0.285714	87.87879	0.73	0.1951	<0.0001
***Kara PadaTalaDaha* (Burning sensation in palms and soles)**								
	V0	V1	V2	V3	% Diff	SD	SE	P' Test
Group-I(n=19)	2.263158	1.894737	1.842105	1.736842	23.25581	0.513	0.1177	0.0003
Group-II(n=14)	2	1.357143	0.642857	0.642857	67.85714	0.6333	0.1693	<0.0001

Group-III (n=14)	2.285714	1.571429	0.5	0.428571	81.25	0.7703	0.2059	<0.0001

Table 1: Effect of study medication on Ayurvedic symptoms score-

Effect of study medication on Cholesterol-
No significant improvement was observed in Group-1 (control group) till the end of day 180. A significant difference (0.0175 Kruskal-Wallis test (Nonparametric ANOVA)) in Group-II and a highly significant difference (<0.0001 Kruskal-Wallis test (Nonparametric ANOVA)) was observed in Group-III. These results are shown in figure 5.

Effect of study medication on Triglycerides- No significant improvement was observed in Group-1(control group) till the end of day 180. A slight difference (0.8438 Kruskal-Wallis test (Nonparametric ANOVA)) in Group-II and a highly significant difference (0.0016 Kruskal-Wallis test (Nonparametric ANOVA)) was observed in Group-III. The results are shown in figure 6.

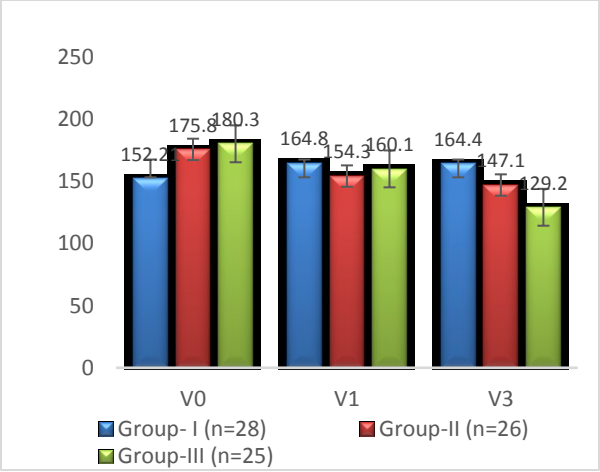


Figure 5: Effect of study medication on Cholesterol

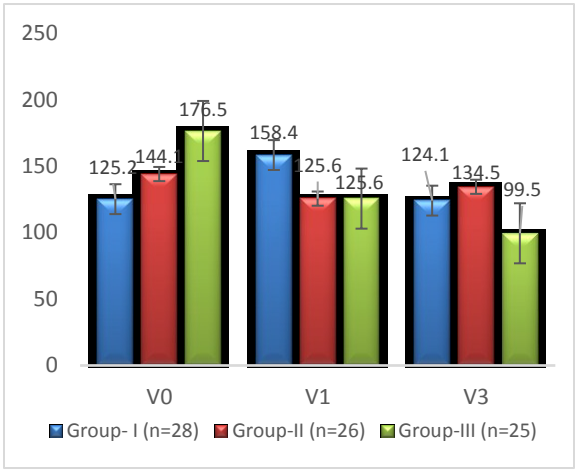


Figure 6: *Effect of study medication on Triglycerides*

Effect of study medication on HDL- No improvement in terms of serum HDL level was seen in Group-I (control group) or study Group-II. A slight increase in HDL level was observed in Group-III, the results are shown in figure 7

Effect of study medication on LDL- No significant improvement was observed in Group-1 (control group) till the end of day 180. A significant difference (0.013 Kruskal-Wallis test Nonparametric ANOVA)) in Group-II and a highly significant difference (0.0003 Kruskal-Wallis test (Nonparametric ANOVA)) was observed in Group-III. The results are shown in figure 8.

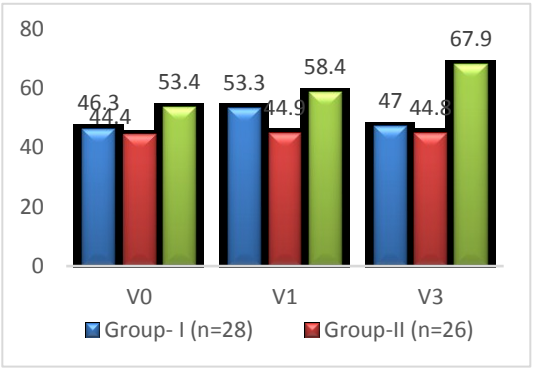


Figure 7: *Effect of study medication on HDL*

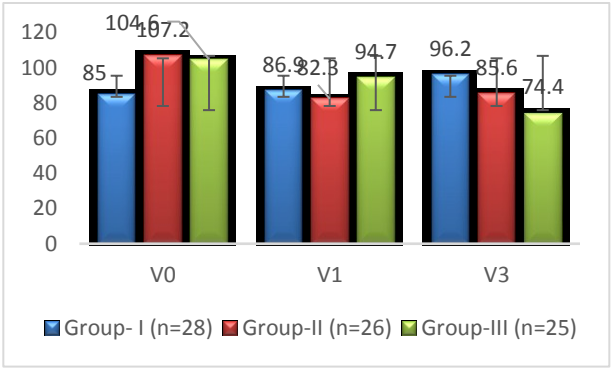


Figure 8: Effect of study medication on LDL-

DISCUSSION

Type II diabetes is characterized by a progressive deficit in β cell function and mass with increased β cell apoptosis[5]. Islet amyloid in T2DM is composed primarily of a 37-amino acid protein, islet amyloid polypeptide (IAPP)[6]. Islet amyloid polypeptide fibers or oligomers have role in progressive failure of B cells in type -2 diabetes also they have cytotoxic property, this disruption of membranes with islet amyloid polypeptide (IAPP) toxic oligomers of the secretory pathway in a novel mechanism to count for cellular dysfunction and apoptosis in type-2 diabetes[7 & 8]. These blockages caused by islet amyloid polypeptide (IAPP) may be co-related with the concept of *Aam* (toxins) described in ancient Ayurveda texts produced by *dhatvagni Mandya* (low metabolic fire).

Probable mode of action of Diabetox – Virechan -

Ayurveda has mentioned some metabolic disorders like *Madhumeh, Sthouly, Dhamanipralep* etc. Ayurveda has also mentioned that improper functioning of Agni (Digestive fire) causes Aam (toxins). Vitiated *Doshas* and *Dhatus* along with this Aam, causes blockages in channels. Later on, they lead to metabolic diseases like *Madhumeh* etc.

Panchakarma is one of the many options of Ayurveda to treat metabolic diseases. *Virechan* (Detoxification) is one of its bio purification methods: this purification treatment is able to return the body system to homeostasis, to rejuvenate the body and it also facilitates the desired pharmacotherapeutic effect of medicines[9]. Detoxification removes blockages present in the pancreatic channels if they are formed by islet amyloid polypeptide (IAPP) toxins.

A significant decrease in serum cholesterol and triglycerides levels were seen, with an increase in HDL cholesterol levels, thus we were able to control the hyperlipidaemic state in *Madhumeh* – Diabetes Type 2 patients.

E. littorale has a protective effect on nerve function and oxidative stress (N M Bhatt et.al) in diabetic neuropathy. *Swertia Marin* is a potential hypolipidaemic agent as it possesses high antiatherogenic potential and an effective cholesterol lowering agent which inhibits HMG-Co A reductase [10 & 11] *A. Marmelos* has a hypoglycaemic effect; and *A. Marmelos* shows significantly increased insulin levels in histological studies by increasing insulin- immunoreactive β- cells [12]. *A. marmelos* has an anti-diabetic activity by reducing blood sugar levels, glycated haemoglobin, cholesterol, triglyceride, LDL, it increases serum insulin level, and it also has a hyperlipidaemic and antioxidant effect [13].

G. sylvestre has a significant impact on blood sugar levels, glycated haemoglobin A1c, it also has lipid lowering properties and the property to improve anthropometric measures. *G. sylvestre* reduces blood sugar, glycated haemoglobin, polyphagia, fatigue, and even produces significant changes in lipid profile [14].

Zingiber officinale, Piper longum and Piper nigrumare, due to their bioavailability, enhance the actions of other medicaments. *Trikatu* is a potent hypolipidaemic agent[15]. *P. marsupium* has an effective role in lowering plasma glucose, cholesterol, triglycerides; hence exhibits significant anti diabetic activity which resembles insulin like properties [16]. Liquiritigenin and pterosupin give significant results in lowering cholesterol, triglyceride and LDL[17]. *T. Foenum graecum* seed improves metabolism and has hypoglycaemic and hypolipidemic effects [18].

M. charantia improves insulin secretion, has a hypoglycaemic effect and can improve glucose intolerance [19]. *Curcuma longa* accounts significant reduction in glycated haemoglobin. In neuropathy it can reduce diabetes complications and inflammation by reducing CRP, and it has a hypolipidemic action and antioxidant property [20]. *E. officinalis* has scope to treat both general and diabetic dyslipidemia, it improves high density lipoprotein, and lowers low density lipoprotein cholesterol levels [21, 22].

CONCLUSION

This present study shows that when both the tablets *Madhunil (Diabhar)* and *Madhuyog (Sugarid)* were administered in newly diagnosed *Madhumeh* – Diabetes Type 2 patients, they were able to significantly decrease the hyperglycaemic and hyperlipidaemic conditions without any toxic- or side effect. Hence

these combinations are potential candidates for the treatment of type II Diabetes mellitus. We were able to minimise the dose of OHA when these polyherbal formulations were used along with *Virechan* (Detoxification), and we were also able to reduce the complications. The above clinical trial reports the hypoglycaemic and hypolipidaemic effect of the polyherbal combinations *Madhunil (Diabhar)* and *Madhuyog (Sugarid)*.

REFERENCES

1. Diabetes.co.uk The global Diabetes community. Https: //www. diabetes.co.uk/global-diabetes/diabetes-in-india.html
2. Why Diabetes loves Indians? Dr. Prabha Acharya Practo, https://www.practo.com/healthfeed/why-diabetes-loves-indians-32667/post
3. Banerjee S1, Sinharoy K, Singh AK. Oral hypoglycaemic agent failure. Oral hypoglycaemic agent failure. 2002 Jul; 100(7):452-6.
4. Diabetes Prevention Program Research Group. Reduction in the Incidence of type 2 diabetes with life-style intervention or metformin. N Engl J Med 2002; 346:393-403.
5. Leena Haataja, Tatyana Gurlo, Chang J. Huang, Peter C. Butler, Islet Amyloid in Type 2 Diabetes, and the Toxic Oligomer Hypothesis, Endocrine Reviews, Volume 29, Issue 3, 1 May 2008, Pages 303–316, https://doi.org/10.1210/er.2007-0037
6. Tatyana Gurlo, Evidence for Proteotoxicity in β Cells in Type 2 Diabetes: Toxic Islet Amyloid Polypeptide Oligomers Form Intracellularly in the Secretory Pathway, The American Journal of Pathology Volume 176, Issue 2, February 2010, Pages 861-869, https://doi.org/10.2353/ajpath.2010.090532
7. Per Westermark, Arne Andersson, and Gunilla T. Westermark, ISLET AMYLOID POLYPEPTIDE, ISLET AMYLOID, AND DIABETES MELLITUS, Published Online:01 JUL 2011https://doi.org/10.1152/physrev.00042.2009
8. TatyanaGurlo, Evidence for Proteotoxicity in β Cells in Type 2 Diabetes: Toxic Islet Amyloid Polypeptide Oligomers Form Intracellularly in the Secretory Pathway, The American Journal of Pathology,Volume 176, Issue 2, February 2010, Pages 861-869, https://doi.org/10.2353/ajpath.2010.090532
9. Ashutosh Chaturvedi, Effect and Mechanism of Virechana Karma (Therapeutic Purgation) Over Fructose-Induced Metabolic Syndrome: An Experimental Study, Journal of Evidence-Based Complementary & Alternative Medicine 2016, Vol. 21(3) 194-201DOI: 10.1177/2156587215596283
10. Niraj Mukundray Bhatt, Suparna Barua and Sarita Gupta, American Journal of Infectious Diseases 5 (2): 99-105, 2009 ISSN 1553-6203
11. Hitestvaidya, Swertiamarin: A lead from *Enicostemmalittorale* Blume. for anti-hyperlipidaemic effect, European Journal of Pharmacology Volume 617, Issues 1–3, 1 September 2009.
12. Gopalsamy Rajiv Gandhi, Hypoglycemic and β-cells regenerative effects of *Aegle marmelos* (L.) Corr. bark extract in streptozotocin-induced diabetic rats, Food and Chemical ToxicologyVolume 50, Issue 5, May 2012, Pages 1667-1674
13. Kumar V, Ahmed D, Anwar F, Ali M, Mujeeb M. Enhanced glycemic control, pancreas protective, antioxidant and hepatoprotective effects by umbelliferon-α-D-glucopyranosyl-(2(I) → 1(II))-α-D-glucopyranoside in streptozotocin induced diabetic rats. *Springerplus*. 2013; 2:639. Published 2013 Nov 28. doi:10.1186/2193-1801-2-639
14. Gaytán Martínez, Luis A et al. "Effect of *Gymnemasylvestre* Administration on Glycemic Control, Insulin Secretion, and Insulin Sensitivity in Patients with Impaired Glucose Tolerance." *Journal of medicinal food*, 10.1089/jmf.2020.0024. 27 May. 2020, doi:10.1089/jmf.2020.0024
15. R.K. Johri, U. Zutshi, An Ayurvedic formulation 'Trikatu' and its constituents, Journal of Ethnopharmacology, Volume 37, Issue 2, September 1992, Pages 85-91
16. Valsala Sivakumar, Effect of an indigenous herbal compound preparation 'Trikatu' on the lipid profiles of atherogenic diet and standard diet fed Rattusnorvegicus, Phytotherapy Research, Volume 18, Issue 12https://doi.org/10.1002/ptr.1586
17. Dhanabal SP, Kokate CK, Ramanathan M, Kumar EP, Suresh B. Hypoglycaemic activity of Pterocarpusmarsupium Roxb. *Phytother Res*. 2006;20(1):4-8. doi:10.1002/ptr.1819
18. Jahromi MA, Ray AB. Antihyperlipidemic effect of flavonoids from Pterocarpusmarsupium. *J Nat Prod*. 1993;56(7):989-994. doi:10.1021/np50097a001
19. Geberemeskel GA, Debebe YG, Nguse NA. Antidiabetic Effect of Fenugreek Seed Powder Solution

(*Trigonellafoenum-graecum L.*) on Hyperlipidemia in Diabetic Patients. *J Diabetes Res*. 2019; 2019:8507453. Published 2019 Sep 5. doi:10.1155/2019/8507453

20. Cortez-Navarrete M, Martínez-Abundis E, Pérez-Rubio KG, González-Ortiz M, Méndez-Del Villar M. Momordicacharantia Administration Improves Insulin Secretion in Type 2 Diabetes Mellitus. *J Med Food*. 2018;21(7):672-677. doi:10.1089/jmf.2017.0114
21. Asadi S, Gholami MS, Siassi F, Qorbani M, Khamoshian K, Sotoudeh G. Nano curcumin supplementation reduced the severity of diabetic sensorimotor polyneuropathy in patients with type 2 diabetes mellitus: A randomized double-blind placebo- controlled clinical trial. *Complement Ther Med*. 2019; 43:253-260. doi:10.1016/j.ctim.2019.02.014
22. Upadya H, Prabhu S, Prasad A, Subramanian D, Gupta S, Goel A. A randomized, double blind, placebo controlled, multicenter clinical trial to assess the efficacy and safety of Emblica officinalis extract in patients with dyslipidemia. *BMC Complement Altern Med*. 2019;19(1):27. Published 2019 Jan 22. doi:10.1186/s12906-019-2430-y

Source of Support: Nil
Conflict of Interest: None Declared

How to cite this URL: Smita Naram: An Open Labelled, Randomized, Controlled, Proof Of Concept, Comparative Study To Analyzing The Effect Of Polyherbal Formula-tions Viz. Madhunil (Diabhar), Madhuyog (Sugarid) & Diabetox Treatment Plan For The Treatment Of Madhumeh – Diabetes Type 2. International Ayurvedic Medical Journal {online} 2020 {cited November, 2020} Available from: http://www.iamj.in/posts/images/upload/5040_5050.pdf