

A Study to Assess the Add-on Impact of Ayurvedic Management along with Ongoing Conventional Treatment of Diabetes Mellitus: A Randomized Clinical Trial

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Abstract

*Diabetes mellitus is a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia with disbalance of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, action, or both. Diabetes affects millions and thus is a major public health disease among with adults aged 30+. Available treatment although helps but many develop other side effects to complicate the issue. Ayurveda offers options to manage diabetes without complications. Present study is to see the add-on effect of Ayurveda therapy among persons on modern medicines. Ayurveda D4 combination is Jamunbeej and Gudmarpatra 5 gm churna each before breakfast and dinner and Giloy and Nagarmotha, 5 gm churna each after breakfast and dinner with ongoing modern treatment (Group A) and Group B continues on modern medicines with placebo. Treatment allocation is randomized. Once qualified for inclusion, patient is allocated to Group A or to Group B. Of the 66 patients recruited, 51 completed the study. Treatment was given for 12 weeks and monitored every 15th day until 3 months. Assessments of Ayurveda parameters, such as rog bala, agnibala, dehabala, cheatsbala and daytime sleepiness scale, fatigue assessment scale was done, at baseline and 3 months. T-test and nonparametric test used to compare results. Significant improvement in subjective and objective parameters, DSS and FAS is observed in Group A than in Group B. **Conclusion:** Ayurveda D4 combination can be a good treatment strategy to manage diabetes Type 2 well for reasons of safely and good quality of life.*

Keywords: Combination, parameters, Rog bala, Agni bala, Dehabala, Cheats bala

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INTRODUCTION

Diabetes mellitus (DM) or type-2 diabetes is one of the major non-communicable and fastest growing public health problems in the world including India and is also a condition difficult to treat and expensive to manage. The prevalence of diabetes is rapidly rising all over the globe at an alarming rate. It has been projected that the number of diabetes victims in the world will double from the current level of about 190 to 325 million during the next 25 years [1]. The global prevalence of diabetes among adults (18 years of age) has risen from 4.7% in 1980 to 8.5% in 2014 [2]. WHO projects that diabetes will be the seventh leading cause of death in 2030 [2]. Type 2 diabetes makes up about 90% of cases of diabetes with the other

10% due primarily to DM type 1 and gestational diabetes. Obesity is thought to be the primary cause of type 2 diabetes in people who are genetically predisposed to the disease. In Ayurveda, *Medoroga* is said to be the '*Nidanarthakara*' for *Prameha* [3]. It is crystal clear that one important cause of insulin resistance is obesity. The main causes of type 2 DM are sedentary lifestyle, unhealthy eating practices, stress, alcohol and smoking, anxiety and also genetic factors [4]. Though conventional medicines are useful for diabetes but when one drug is not able to control blood glucose levels, other drugs are added to achieve BSL targets that produce progressive insulin resistance and beta cell failure. However, side effects are reported like, diarrhea, nausea, stomach pain, weakness, unusual muscle pain, unusual sleepiness, irregular heart rate etc. [5]. Diabetes is a lifestyle disease that requires the person living with the disease to self-manage and make numerous daily decisions regarding food, activity and medications. Self-management refers to the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Integrating the therapeutic approaches of Ayurvedic medicine and diet changes in the comprehensive care of diabetes is a need of the time. In Ayurvedic Classics, *Madhumeha* is described to be *Asadhya* and irreversible but its complications and side effects of the modern oral hypoglycemic agents (OHA) can be delayed and if present, can be controlled with Ayurvedic formulations. Ayurvedic management of *Madhumeha* (Type 2 DM) aims not only to achieve a good glycaemic control but also to treat the root cause of disease and its prevention. The present study entitled as "An open label double arm clinical trial to determine the efficacy of D4 combination along with ongoing conventional medicine in managing Diabetes Mellitus (Type-2)" is carried out with the following aims and objectives:

Aim

To examine the effect of Ayurvedic drugs in reducing the glycemic levels and improving quality of life in patients suffering from DM with ongoing oral administration of pharmacological drugs.

Primary Objective

To determine the efficacy of the D4 combination therapy along with ongoing conventional medicines compared to that of conventional medicine alone in controlling the level of glycated haemoglobin (HbA1c) and monitoring fasting blood sugar (FBS) and pre-prandial blood sugar (PPBS).

Secondary

To evaluate the safety of the proposed drugs in terms of the adverse effects during the study.

METHODS AND MATERIAL

Proposed treatment is ongoing conventional treatment with or without Ayurvedic treatment Regimen (D4 combination). D4 Combination is inclusive of (i) *Jamunbeej churna* and (ii) *Gudmarpatra churna* each of 5 gm twice a day before breakfast and dinner; the combination of (iii) *Giloy churna* 5 gm and (iv) *Nagarmotha churna* 5 gm, after breakfast and dinner respectively; along with 100 ml of luke warm (35–40°C) water, may help to have glycaemic control in DM patients with ongoing pharmacological drugs.

Rationale

Jamun (Syzygiumcumini (L.))

Jamun (Syzygiumcumini (L.)) seeds have antioxidant potential which may help in reducing free radicals and improving the functions of β -cells of pancreas, thereby reducing the blood glucose levels [6]. According to Ayurveda, *Jamun* is the best *Vatakar* [7] and *Mutrasangrahaniya* [8]. Its *Kashaya* property possess *sangrahi*, *shareerajkle* [9] (decreases fluidity) and thus helps to reduce the frequency of urination.

Gudmar (Gymnemasylvestre R.Br.)

Gudmar (Gymnemasylvestre R.Br.) is, as mentioned in *Bhavprakashanighantu* [10], for *Mehanashak Yoga*. The presence of gymnemic acids, have been reported from the leaves of *G.*

sylvestre which stimulates the secretion of insulin and rejuvenates the process of generating β -cells and produces insulin [11].

Giloy (*Tinosporacordifolia*(Willd.))

Giloy (*Tinosporacordifolia* (Willd.)) is, as mentioned in *Bhavprakash* [12] and *Raj nighantu* [13], for *Pramehahara Chikitsa*. *Giloy* is included in '*Trishnanigrahana Mahakasaya*' by *Charaka* [14]; thus it can be useful in controlling excessive *trishna* (*pipasa*), which is *purvarupas* as well as *Upadrava* of *Prameha*. It is also included in *Dahaprashamana Mahakasaya* [15], so it can be useful in *daha*, a condition found as *Purvarupas* and as *Upadrava* of *Prameha*. It is also having *Agnideepana* (appetite enhancer), *Paachana* (digestive), *Sangrahi* (relieve polyuria), *Medhya* (nerve tonic), *Chakshusya* (eye tonic) properties, associated with symptoms, viz., stress at the working place, fear, uneasiness, loss in lusture etc. Thus, it not only helps the *Agni* (insulin action and sensitivity) to work properly but also nourishes the undernourished tissues of the body (by improving insulin sensitivity, by supplying essential ions like Cl, Zn, Mn etc. and also because of their free radical scavenging effect) and their *Rasayana* effect (anti-oxidant) prevents the oxidative stress related to type-2 diabetes mellitus.

Nagarmotha (*Cyprus rotundus*)

According to Acharya *Charaka*, as mentioned in *Lekhaniya*, *Truptighna* and in *Trishnanigrahan Mahakasay* [16], it reduces excessive *trishna* (*pipasa*) in conditions of *Madhumeha* and it acts on the root cause i.e. *Dhatvagnimandya* and *Santarpan*. It possesses *lekhan* property, which reduces the levels of *kleda* (fluid) and *meda* (fat). It also possesses the *Laghu* and *Ruksha Guna* which balances the *Kapha* and *Pitta*, hence it works as *Samprapti Vighatana*.

Inclusion Criterion

The criteria for diagnosis of DM used are as per American Diabetes Association:

1. Patients of either gender in the age group of 35–55 years.
2. Patients with random blood sugar level (RBS) >200 mg/dl, or
3. Fasting blood sugar (FBS) >126 up to 300 mg/dl, or
4. Postprandial blood sugar (PPBS) >200 up to 450 mg/dl, and
5. Glycosylated haemoglobin index >6.5%.

Newly/Early diagnosed (0–3 year) cases to be included as per following criteria:

1. Patients who are taking conventional treatment for diabetes.
2. Patient accidentally diagnosed in routine check-up or when appeared with other complaints in the hospital.

Exclusion Criterion

- Patients suffering from emergency cases in DM were excluded,
- Patients having insulin dependent DM (IDDM) and receiving insulin (type 1),
- Excessive blood glucose: FBS >300 mg/dl and PPBS >450 mg/dl,
- Patients with any chronic complications like micro vascular and macro vascular were excluded.

Study Size and Randomization

Keeping in view of the availability of patients, it was decided to have 30 patients in each group and with 10% assumed to drop out, a sample of 33 in each group was fixed. Once a patient is qualified for inclusion, the inclusion was randomized. A series of 66 random numbers were selected from Random Number Table [17]. For odd Random number, the patient was allocated to Group A, otherwise to Group B.

Treatment Allocation

The Group A patients were treated with D4 combination along with ongoing conventional medicine and Group B patients were treated with ongoing conventional medicine with placebo capsule

(*Triticum aestivum*). During treatment, the health of the study subjects was monitored in the prearranged time schedule. The changes were recorded in the especially prepared case sheet according to symptom grading and the data records were generated.

Selection of Patients

The clinical study was carried out on patients, attending OPD of Kayachikitsa, AIIA, New Delhi. The patients were allotted different groups according to the obtained randomisation table. The Informed consent was also taken before registering patients in the study. Patients were suffering from classical signs and symptoms of *Prameh/Madhumeha* as stated below:

Prabhutamutrata, Avila-mutrata, with some or on *purvaroopo-Jtilibhavkesesu, Madhuryamaasya, Karpadasuptataadhaho, Mukhatalukanthasosham, Pipasadhikya, Alasya Nidra, Tandra* etc. [18].

Treatment Schedule and Follow up

This clinical study was conducted to determine the efficacy of D4 combination along with ongoing conventional medicines given for 12 weeks (3 months) in the trial and the patients were followed up in every 15 days interval. Assessment of Ayurveda parameters, such as *rog bala, agnibala, dehabala* and *chetasbala* [19], daytime sleepiness scale [20] and fatigue assessment scale [21] was done along with diabetes parameters like FBS, PPBS and HbA1c (%) etc. Although 66 patients were recruited in the study but during the course of study, 15 (22.7%) patients dropped out, thus finally 51 patients were left in the study.

Statistical Analysis

Paired Student' T-test to compare means, before and after treatment within the group, and for comparison between groups, unpaired Student' T-test was used. For qualitative data, nonparametric tests like Wilcoxon matched paired Sign Rank test and Mann Whitney U-test was also used to cross check the outcome results.

RESULTS

Patients Characteristics

Of the total patients who completed the study, 33.3% were in age group 50–55 years and 65.2% males. The work status suggests that 33.3% were engaged in sedentary work, 71.2% of the patients had *vata-kaphapradhanaprakriti*, and 39.4% had family history of DM. The chronicity (Duration) of disease was observed to be 2–3 years in 53.0% of patients. The treatment namely 'Metformin+Glimepiride' was being taken by 50% only.

Changes in Objectives Parameters

In Group A, Fasting blood sugar (FBS) level was 222.0 before treatment which declined to 187.4 after the intervention, showing 15.6% improvement (Paired T-test=3.68, $p<0.001$). However, FBS levels in Group B did not decline; thus effect of intervention in Group A is significantly high (T-test=3.0, $p<0.001$). The level of PPBS in Group A also declined by 17.9%, significantly from 351.8 to 288.7 (Paired T-test=4.33, $p<0.001$), but in Group B, PPBS raised by 5.9%. This again shows that achievement in Group A is better than Group B. Similar results were seen with reference to HbA1c, decline by 11.3% in Group A vs. no decline in Group B and urine sugar levels declined by 97.4% in Group A but only 16.7% in Group B. In both cases, effect of treatment intervention in Group A shows significantly better results (Table 1).

Changes in Subjective Parameters

In improving classical symptoms of *Prameha*, D4 combination along with ongoing conventional medicine in Group A showed highly significant improvement in *Prabhoot-mutrata* (83.0%), *Avila-mootrata* (93.1%), *Kshudhaadhikya* (85.4%), *Pipaasadhikya* (81.8%), *Daurbalya* (84.9%), *Suptaangata/daaha* (88.7%), *Pindikodveshtana* (80.2%), *Alasya* (77.5%), *Sweda* (76.4%), *Madhuraashyata* (77.0%). However, In Group B, ongoing conventional medicine showed significant

Table 1. Change (BT vs. AT) in Mean Scores in Objectives Parameters of Diabetes.

Parameter	Group A (N=26)				Group B (N=25)				Between Group Comparison
	BT	AT	Improvement (%)	t-test, p-value	BT	AT	Improvement (%)	t-test, p-value	(BT-AT) ₁ -(BT-AT) ₂ , t-test, p-value
FBS	222.0	187.4	15.6	3.68, <0.001	182.2	185.2	-1.7	0.4, >0.7	37.6, 3.0, <0.001
PPBS	351.8	288.7	17.9	4.33, <0.001	269.7	285.7	-5.9	-1.9, >0.7	79.2, 4.6, <0.001)
HbA1c	10.44	9.26	11.3	4.55, <0.001	8.47	8.48	-0.01	-0.11, >0.9	1.19, 4.2, <0.001
Urine Sugar	1.57	0.04	97.4	5.63, <0.001	0.48	0.40	16.7	0.37, >0.7	1.45, 4.17, <0.001

Table 2. Change (BT vs. AT) in Mean Scores in Subjective Parameters Related to Diabetes.

Parameter	Group A (N=26)				Group B (N=25)				Between Group Comparison
	BT	AT	Improvement (%)	t-test p-value	BT	AT	Improvement (%)	t-test, p-value	(BT-AT) ₁ -(BT-AT) ₂ , t-test, p-value.
Prabhut-mutrata	2.23	0.38	83	15.4, <0.001	2.08	1.40	33.0	3.8, <0.001	1.16, 5.4, <0.001
Avila-mutrata	0.58	0.04	93.1	3.4, <0.01	0.40	0.32	20.0	0.70, >0.5	0.45, 2.32, <0.01
Kshudh-adhikya	2.12	0.31	85.4	12.3, <0.001	2.08	1.44	30.8	4.57, <0.001	1.17, 5.8, <0.001
Pipaasadhikya	2.31	0.42	81.8	12.6, <0.001	1.60	1.12	30.0	3.11, <0.01	1.40, 6.5, <0.001
Daurbalya	2.31	0.35	84.9	13.9, <0.001	1.60	1.52	05.0	0.52, >0.6	1.88, 9.1, <0.001
Suptaangata/daaha	2.04	0.23	88.7	12.3, <0.001	1.80	1.24	31.1	3.93, <0.001	1.24, 6.1, <0.001
Pindiko-dweshtana	1.92	0.38	80.2	9.7, <0.001	1.52	0.84	44.7	5.42, <0.001	0.85, 4.2, <0.001
Vibandha	0.81	0.46	43.2	1.88, >0.07	1.40	1.36	2.86	0.37, >0.71	0.31, 1.42, >0.05
Aalasya	2.58	0.58	77.5	18.0, <0.001	2.12	1.64	22.7	3.36, <0.01	1.52, 8.4, <0.001
Sweda	2.12	0.50	76.4	11.8, <0.001	2.12	1.32	35.3	5.86, <0.001	0.90, 4.9, <0.001
Madhur-aashyata	1.65	0.38	77.0	7.0, <0.001	1.40	0.96	31.4	3.38, <0.01	0.82, 3.7, <0.001

improvement in *Prabhootmutrata* (33.0%), *Kshudhaadhikya* (30.8%), *Suptaangata/daaha* (31.1%), *Pindikodveshtana* (44.7%), *Sweda* (35.3%), *Pipaasadhikya* (30.0%), *Alasya* (22.7%), *Madhur-aashyata* (31.4%). The comparison of Group A vs. Group B, reveals that improvement resulted by adding on D4 combination has caused significantly higher improvement in all except *Vibandha* (Table 2).

Impact on Agni bala, Dehabala and Chetasbala

Data presented in Table 3 shows that in Group A, the improvement in *Agni bala* such as *Jaranashakti* (71.1%), *Abhyavaharanshakti* (74.0%), *Ruchihaaharkale* (75.3%), *Balavridhhi* (73.2%), *Sharirupchya* (55.8%), *Nidralabhoayathakala* (50.3%), *Sukhenchapratibodhnam* (56.9%), *Manobuddhindriyaavyapad* (68.6%) respectively. However, in Group B, improvement in *Jaranashakti* (30.3%), *Manobuddhindriyaavyapad* (27.8%) respectively but no significant change

was observed in parameters like *Avila mootrata* (20.0%), *Balavridhi* (20.4%), *Daurbalya* (5.0%), *Vibandh* (2.86%), *Abhyavaharanshakti* (4.3%), *Ruchihaaharkale* (0%), *Sharir-upchya* (7.04%), *Nidralabhoyathakala* (0.7%), and *Sukhenchapratibodhnam* (2.2%).

Improvement in Day Time Sleepiness Scale (DSS) [20] and Fatigue Assessment Scale (FAS) [21]

The data presented in Table 4 suggests that although both the Daytime Sleepiness Scale (DSS) Score and Fatigue Assessment Scale (FSS) have shown significant improvement in both the Groups but improvement in DSS (37.0 vs. 13.0%) and in FAS Score (39.4 vs. 16.3%) is more in Group A than in Group B. With reference to both parameters, Group A appears to be superior than Group B.

DISCUSSION

Prameha is mainly caused by *Bahu Drava Shleshma* and *Bahu-abaddhaMeda* [22]. As *Prameha* is *Kleda-pradhanavyadhi* the main focus should be on *kledashoshan-chikitsa*. Thus *Katu*, *Tikta* and *Kashaya Rasa dravyas* are ideal drugs to treat *Prameha*. *Tikta*, and *kashaya rasa* due to *ushna* and *tikshnaguna* are *kaphashamaka*, absorbs *medadhatu* and also *shareeraja-kleda*, the important factor involved in *Tikta* and *katu rasa* also by its *deepana* (digestive stimulant) and *pachana* (digestant)

Table 3. Impact on Agnibala, Dehabala and Chetasbala.

Parameter	Group A (N=26)				Group B (N=25)				Between Group Comparison
	BT	AT	Improvement (%)	t-test p-value	BT	AT	Improvement (%)	t-test p-value	$(BT-AT)_1-(BT-AT)_2$, t-test, p-value.
Agni bala									
<i>Jaranashakti</i>	1.35	0.39	71.1	9.3, <0.001	1.32	0.92	30.3	4.0, <0.001	0.56, 3.9, <0.001
<i>Abhyavaharanshakti</i>	1.19	0.31	74.0	6.9, <0.001	0.92	0.88	4.3	1.0, >0.32	0.84, 6.2, <0.001
<i>Ruchihaaharkale</i>	1.58	0.39	75.3	8.1, <0.001	1.04	1.04	0	0	1.19, 7.4, <0.001
Dehabala									
<i>Balavridhi</i>	2.31	0.62	73.2	12.7, <0.001	1.96	1.56	20.4	2.8, <0.01	1.29, 6.7, <0.001
<i>Sharir-upchya</i>	0.77	1.20	55.8	6.35 <0.001	0.54	0.50	7.40	-7.40 >0.82	0.39 1.0, >0.12
Chetasbala									
<i>Nidralabhoyathakala</i>	1.85	0.92	50.3	4.1, <0.001	1.80	1.68	0.7	0.29 >0.52	0.80, 2.8, <0.01
<i>Sukhenchapratibodhnam</i>	2.04	0.88	56.9	-6.36 <0.001	1.80	1.76	2.2	0.30 >0.77	1.11, 4.9, <0.001
<i>Manobuddhindriyaavyapad</i>	2.39	0.77	68.6	12.9 <0.001	2.16	1.56	27.8	6.00 <0.001	1.02, 6.3, <0.001

Table 4. Change (BT vs. AT) in Mean Scores in DSS and FAS of Diabetes.

Parameter	Group A (N=26)				Group B (N=25)				Between Group Comparison
	BT	AT	Improvement (%)	t-test p-value	BT	AT	Improvement (%)	t-test, p-value	$(BT-AT)_1-(BT-AT)_2$, t-test, p-value
DSS	13.92	8.77	37.0	10.8, <0.0001	13.84	12.04	13.0	2.35, <0.02	3.35, 3.8, <0.001
FAS	28.04	17.00	39.4	12.4, <0.001	24.80	20.76	16.3	3.91, <0.001	7.0, 5.2, <0.001

action improves the impaired metabolism which involves in the pathogenesis of *Prameha*. The D4 combination of the drugs is having follows target approach and impact at *jathara-agni* level, at *dhatava-agni* level, and *Rasayana* effect. Since the trial drug (D4 combination) given in Group A is having *Tikta, Katu, Kashaya Rasa, Laghu, Ruksha, Tikshna Guna, Ushna Veerya, Katu Vipaka* which pacify the *kapha-dosha* and *kleda* in the body and *Prameha* being *tridoshaja Vyadhi*, D4 combination is proved to be giving significant impact. *Katu rasa* is *shoshaka, sneha-sweda-kledahara* and *kaphashamaka* [23], *Tikta rasa* is *kleda-meda-vasa-majja-puya-mutra-purish-pitta-shlasamashoshak* [24] and *Kashaya rasa* is *sangrahi, stambhana, sleshama-rakta-pitta prasaman* and *sharer kledashoshaka* [25]. Although Acharyas have mainly emphasized on vitiation of *Kapha-Dosha, Medovridhi* because of *Shaithilya* and *Medodhatv-agnimandhya*; but when it is not controlled effectively, the vitiation of *vata* due to *avarana* of *medodhatu* takes place and ultimately it converts into all *Prameha* and in chronic course of disease progresses on to *Madhumeha* (a sub-type of *Vataj Prameha*) due to *dhatukshayajanyavataparakopa*. Most of the drugs in this combination have *deepana, pachana* and *lekhana* properties, which help to clear *Dhatvagnimandyajanita Ama* as have been discussed earlier and breaks the *Samaprapti* (etiopathogenesis) of *Prameha*. These properties also help in *Tikta, Katu, Kashaya Rasa, Laghu, Ruksha Guna, Ushna Virya* and *Katu Vipaka* which rectify *kaphadushti* and *medodhatudushti*. Further, the drug combination is *Tridoshashamaka* (mainly *pitta-kaphahara*), and thus helped in correcting *vataushti*. With *laghu* and *rukshaguna* it acts as *Kledashoshak* and *Mootrasangrahaniya*. *Lekhan karma* (*nagarmotha*) alleviates the *bahu-abaddhameda* and associated *mamsadhatu*. By alleviating the *bahu-abaddhameda* it helps in reducing *atisweda*. *Katu, tikta*, and *kasaya rasa* play an important role in reducing excessive *kleda* and *meda*. These properties ultimately help in alleviating *Prabhoota-avilamutrata* (increased turbid urination), *Kshudhaadhikya* (polyphagia) and *Pipasaadhikya* (polydipsia) in acute diabetic stage. *Vatashamaka* property of trial drugs helps in relieving *karapadasupti* whereas *khapha-pittagnaguna* of drugs helps in *daha shaman*. With its *ushnaveerya, anulomana* and *vedana-sthapana* properties it provides relief in *Pindikodveshtana* by *vata shaman*. The D4 combination possessed potent hypoglycemic activity due to which it provided improvement in fasting (FBS) and post prandial glucose levels (PPBS), glycated hemoglobin (HbA1c) and urine sugar.

Role of *Pathya Apathy* in *Prameha*

The *pathya* and *apathya* regimen was prescribed to the patients along with the medication in terms of *aahara* and *vihara*. It played an important role in providing relief from ailments. Especially, *yavapradhanaahar* was advised to patients. It showed a very high level of improvement along with the medications. Equal importance was given for the things not to be done. As even if the patient is taking proper medications, but if he/she is unable to stop himself/herself from eating foods with high glycemic index or having a sedentary lifestyle, the desired results are not achieved. The observation was continued up to 3 months; during this period, their sugar level remained under control. Now, patients are living a normal life but somewhat alert for diet, exercise and morning walk (45 min) which is certainly a better way to remain healthy.

CONCLUSION

In this study both groups of patients were suggested to continue on healthy diet and life style changes along with the Ayurvedic D4 combination with conventional anti-diabetic drugs. The results of the study clearly suggest that outcome in Group A is significantly better than in Group B. Thus, it can be confidently concluded that Ayurveda D4 combination may contribute significantly to achieve control on blood sugar levels and improvement in the quality of life in patients of diabetes mellitus type 2 with reference to decline in *Rogbala*, increase in *Agnibala, dehabala* and *cheats bala* and to check its complications to have overall improved quality of life.

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REFERENCES

1. Wild S, Roglic G, Green A, Sicree R, King H. Global Prevalence of Diabetes: Estimates for the Year 2000 and Projections for 2030. *Diabetes Care*. May 2004; 27(5): 1047–53p.
2. Mathers CD, Loncar D. Projection of global mortality and burden of disease from 2002 to 2030. *PLoS Med*. 2006; 3(11): e442p.
3. Prasad SR, editor. Aetiopathology of Madhumeha. Dec 2000; 1–16p. [<https://www.researchgate.net/publication/259675318>].
4. <http://youthonhealth.com/type-2-diabetes-a-lifestyle-disease>. Accessed on 2/6/2018 at 6 pm.
5. slowiczek, Side Effect of Metformin : pharmd on sep. 23, 2016 [<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4214027/>].
6. Gajera HP, Gevariya SN, Hirpara DG, et al. Antidiabetic and Antioxidant Functionality Associated with Phenolic Constituents from Fruit Parts of Indigenous Black Jamun (*Syzygiumcumini* L.) Landraces. *J Food Sci Technol*. 2017; 54(10): 3180–3191p.
7. RK Sharma, VB Dash, editor. Charaka Samhita of Charaka. Sutrasthana; Chapter 25, Verse 40. Vol. I. Reprint 2016 Edn. Varanasi: Chowkhamba Sanskrit Series; 2016; 425p.
8. Shastri K, Chaturvedi G. Charak Samhita of Agnivesha. Part-1, Sutra Sthana; Chapter-4, Verse-33. Varanasi: Chaukhambha Bharati Academy; 2005; 89p.
9. RK Sharma, VB Dash, editor. Charaka Samhita of Charaka. Sutra Sthana; Chapter 26, Verse 43. Vol. I. Varanasi: Chowkhamba Sanskrit Series; 2016.
10. Chunekar KC, Lt. Pandey GS, editor. Bhavamishra. Bhavaprakasha Nighantu, Guduchyadivarga, verse 217. Reprint Edn. Varanasi: Chaukhamba Bharati Academy; 2015.
11. Thakur, et al. Gymnemasylvestre: An Alternative Therapeutic Agent for Management of Diabetes. *J Appl Pharm Sci*. 2012; 2(12): 001–006p.
12. Chunekar KC, Lt. Pandey GS, editor. Bhavamishra. Bhavaprakasha Nighantu, Guduchyadivarga, verse 9. Reprint Edn. Varanasi: Chaukhamba Bharati Academy; 2015; 257p.
13. Tripathi ID, editor. Raja Nighantu with Dravya Guna Prakashika Commentary, Guduchyadivarga. Verse 17. 8th Edn. Varanasi: Chaukhambha Krishnadasa Academy; 2005; 30p.
14. Shastri K, Chaturvedi G. Charak Samhita of Agnivesha. Part-1, Sutra Sathana; Chapter-4, Verse-29. Varanasi: Chaukhambha Bharati Academy; 2005; 87p.
15. Shastri K, Chaturvedi G. Charak Samhita of Agnivesha. Part-1, Sutra Sathana; Chapter-4, Verse-41. Varanasi: Chaukhambha Bharati Academy; 2005; 93p.
16. Shastri K, Chaturvedi G. Charak Samhita of Agnivesha. Part-1, Sutra Sathana; Chapter-4, Verse-3, 11, 29. Varanasi: Chaukhambha Bharati Academy; 2005; 72, 80, 87p.
17. Visweswara Rao K. Biostatistics in Brief Made Easy. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd.; 2010; 307p.
18. Shastri K, Chaturvedi G. Charak Samhita of Agnivesha. Part-1, nidansathana; Chapter-4, Verse-47. Varanasi: Chaukhambha Bharati Academy; 2013; 640p.
19. Acharya Trikmji Y, editor. Charak Samhita of Charak. Vimanasthana, Chapter-8, Verse-89. 2nd Edn. Varanasi: Chaukhambha Surbharati Prakashan; 2005; 275p.
20. Johns M, Hocking B. Daytime Sleepiness and Sleep Habits of Australian Workers. *Sleep*. 1997; 20(10): 844–849p.
21. <https://www.wasog.org/educational-material/fatigue-assessment-scale.html>. Accessed on 2/4/2020 at 4 pm.
22. Shastri K, Chaturvedi G. Charak Samhita of Agnivesha. Part-1, nidansathana; Chapter-4, Verse-6, 7. Varanasi: Chaukhambha Bharati Academy; 2013; 632p.
23. Shastri K, Chaturvedi G. Charak Samhita of Agnivesha. Part-1, Sutra Sathana; Chapter-26. Varanasi: Chaukhambha Bharati Academy; 2013; 506p.
24. Shastri K, Chaturvedi G. Charak Samhita of Agnivesha. Part-1, Sutra Sathana; Chapter-26. Varanasi: Chaukhambha Bharati Academy; 2013; 506–507p.
25. Shastri K, Chaturvedi G. Charak Samhita of Agnivesha. Part-1, Sutra Sathana; Chapter-26. Varanasi: Chaukhambha Bharati Academy; 2013; 507p.