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Clinical efficacy of *Shankhapushpi* and a herbo-mineral compound in type-II diabetes

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Abstract

Diabetic population is more than 245 million worldwide and expected to be >380 million by 2025. One of the main causes of increasing rate of diabetes is stress and tension in day-to-day life, disturbing the homeostasis of positive and negative emotions to initiate pathophysiology of stress-induced diabetes. In the present study, in Group A of 34 patients, a herbo-mineral compound containing *Shuddha Shilajatu, Shuddha Guggulu, Vijayasara Ghana, Saptarangi Ghana*, and *Triphala Ghana* was administered in the dose of 3 gm/day in three divided doses with luke-warm water before meal for the duration of 8 weeks, which significantly relieved symptoms (60.52%) like *Prabhuta Mutrata* (54.55%), *Avila Mutrata* (66.67%), *Daurbalya* (61.36%), *Shrama* (59.32%), etc. with fasting blood sugar (4.05%) and postprandial blood sugar (9.95%). In another series of 34 patients (Group B), where psychological health promoting drug *Shankhapushpi* was administered in the dose of 1.5 gm/day in three divided doses for 8 weeks along with herbo-mineral compound. The percentage relief was found to be more better on symptoms (71.13%) like *Prabhuta Mutrata* (76.92%), *Avila Mutrata* (83.33%), *Daurbalya* (75%), *Shrama* (70.37%), fasting blood sugar (18.04%) and postprandial blood sugar (27.75%). Group B showed better results on psychological parameters like disturbed *Manasabhava* (29.16%) and Brief Psychiatry Rating Scale (38.28%). The high significance of χ^2 (15.50) on overall effect of therapy indicated better results in group B.

Key words: Herbo-mineral compound, *Medhya Rasayana,* psychological factors, *Shankshapushpi,* Type-II diabetes mellitus

Introduction

The dawn of the new millennium is witnessing an unprecedented spread of diabetes in every corner of the globe. Since 1985, the number of people with diabetes worldwide has grown from 30 million to 285 million. It is estimated that 3.5 million people die due to diabetes or its complications annually.[1] While diabetes continues to spread rapidly in the United States and Europe, its impact on the developing world is even more profound and devastating. The World Diabetes Foundation expects 80% of new cases of diabetes to emerge in the developing world due to stressful and sedentary lifestyle as a result of rapid modernization. 90-95% of diabetics have type-II diabetes.[2]

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Modern medical science had a spectacular achievement in the control of blood glucose of diabetics; still high risk exists due to its several side effects. The psychological problems associated with diabetes are treated with long-term use of sedatives and anxiolytic drugs which may lead to hazardous effects on psychological health and produce drowsiness, impair motor functions, loss of memory, nonsocial behavior, etc. Moreover, these drugs produce drug dependency and drug resistance. Therefore, it is need of the hour to think from the Ayurvedic point of view for a better management of mental health in diabetes mellitus (DM).

Type-II diabetes can be covered under *Avaranajanya Madhumeha* described in Ayurveda. In the pathogenesis of *Madhumeha*, provoked *Vata* excretes the *Dhatus* and *Ojas* with *Mutra* (urine) from *Mutravaha Sotas*, involving *Medodhatvagni* and *Meda*, *Mamsa*, *Rasa*, *Kleda*, etc.[3] A herbo-mineral compound (HMC) containing *Shuddha Shilajatu* (*Asphaltum punjabinum*), *Shuddha Guggulu* (*Commiphora wightii* Arn.), *Ghana* (water-soluble extract) of *Triphala* (three myrobalan), *Vijayasara* (*Pterocarpus marsupium* Roxb.), and *Saptarangi* (*Casearia*

esculenta Roxb.) and Saptarangi (Casearia esculenta Roxb.) was selected to evaluate the efficacy in type-II DM patients. The ingredients of compound not only have antihyperglycemic effect, but also correct the vitiated *Dosha*, *Dushya*, *Dhatvagni*, and *Srotas*, along with *Rasayana* (rejuvination) properties to compensate *Dhatukshayatmaka* and *Ojokshayatmaka* effects of the disease.[4]

It is well established that disturbed psychological factors affect the development and progression of type-II DM being a psychosomatic disorder. So, to alleviate worry, sorrow, anger, anxiety, fear, etc., the *Medhya Rasayana* (MR)-*Shankhapushpi*[5] (*Convolvulus pluricaulis* Choisy.) was administered along with HMC to see how far it is capable of potentiating the antidiabetic effect of HMC by counteracting the stress and improving the mental health of diabetic patients.

Materials and Methods

Total 93 patients of type-II diabetes, attending the OPD/IPD of Institute for Post Graduate Teaching and Research in Ayurveda Hospital, Jamnagar, whose blood glucose level was found high and fulfilled the criteria of selection, were randomly distributed in two therapeutic groups.

Group A

HMC was administered to 48 patients in a dose of 3 g/day in three divided doses in pill form for the duration of 8 weeks with lukewarm water before meal.

Preparation of HMC

Ghana (aqueous extract) of *Triphala*, heart wood of *Vijayasara*, and roots of *Saptarangi*, were prepared by following classical guidelines. *Shuddha Shilajatu* and *Shuddha Guggulu* in equal proportion was mixed to the *Ghana* and 500 mg pills were prepared. *Ghana* (aqueous extract) of *Triphala* fruits, *Vijayasara* heart wood, and *Saptarangi* root were prepared by following classical guidelines; mixed with *Shuddha Shilajatu* and *Shuddha Guggulu* in equal proportion and 500 mg pills were prepared.

Group B

HMC as above with MR-*Shankhapushpi* in a dose of 1.5 g/day in three divided doses was administered to 45 patients for 8 weeks (HMC + MR).

Preparation of MR

To augment the potency, seven *Bhavana* of *Shankhapuspi Swarasa* (juice) were given to *Churna* (powder) of its *Panchanga* (whole plant) and 500 mg capsules were filled.

Follow-up

After completion of therapy, patients were advised to visit OPD every week for follow-up up to 1 month, and as per the need, routine O.P.D. treatment was given to them.

Inclusion criteria

The new patients fulfilling the diagnostic criteria of World Health Organization for DM described as under were selected:[6]

- Symptoms of DM and random blood glucose >200 mg/dl or
- Fasting blood glucose >126 mg/dl or
- Postprandial (PP) blood glucose >200 mg/dl at an interval of first 2 h during an oral glucose tolerance test.

Criteria for high blood glucose: The diagnosed patients who were taking allopathic medicine but their blood glucose was not under control were included.[7]

- Fasting blood glucose >6.0 mmol/l (>108 mg/dl)
- 2-h PP blood glucose >8.0 mmol/l (>144 mg/dl)

A detailed proforma covering all signs and symptoms of type-II diabetes, supported with positive and negative *Manasabhava* and Brief Psychiatry Rating Scale (BPRS) was prepared to study the disturbed psychological factors from Ayurvedic as well as modern point of view.

Exclusion criteria

1. Patients of type-I diabetes.
2. Endocrinopathies like acromegaly, Cushing's syndrome, hyperthyroidism, etc.
3. Drug or chemical (glucocorticoids, thiazides, etc.) induced DM.
4. Certain genetic syndromes associated with diabetes, e.g., Down's syndrome, Turner's syndrome, etc.
5. Associated with complications like nephropathy, ketoacidosis, etc.

Investigations

Biochemical investigations like routine hematological investigations to rule out pathological conditions, blood sugar (fasting and PP) for the present state of disease, lipid profile [serum cholesterol, serum triglyceride, High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Very Low Density Lipoprotein (VLDL)] to evaluate the *Dushti* of *Meda*, blood urea and serum creatinine to assess the functional status of kidney, and examination of urine were conducted wherever possible.

Criteria for assessment

- To assess the relief in all symptoms, disturbed *Manasabhava* and parameters of BPRS were scored depending upon their severity in the following manner before and after the treatment.

Not present/absence of symptoms	0
Very mild	1
Mild	2
Moderate	3
Moderately severe	4
Severe	5
Very severe	6

- Biochemical parameters were investigated before and after the treatment to assess the improvement.
- The overall effect was assessed on the basis of relief in symptoms, decrease in raised blood sugar level, improvement on disturbed *Manasabhava* and BPRS. Each criterion has been given equal importance. Thus, the total effect of therapy was marked as:

  Control of disease: Fasting blood sugar (FBS) and postprandial blood sugar (PPBS) coming down to normal limits, with 80% and above improvement in overall effect of therapy

  Markedly improved: Patient showed improvement between 60% and <80%.

Moderately improved: Improvement between 40% and <60%.
Improved: Improvement between 20% and <40%.
Unchanged: No relief or improvement was less than 20%, was taken as unchanged.
To calculate χ^2, the adopted criterion for improvement is equal to or more than 40% of relief from the initial value.

Results and Observations

In group A out of 48 registered patients, 34 had completed the treatment, whereas in group B out of 45 registered patients, 34 had completed therapy.

In group A, highly significant relief was obtained in *Prabhuta Mutrata* (polyuria), *Kshudhadhikya* (polyphagia), *Trishadhikya* (polydipsia), *Kara-Pada Tala Suptata* (numbness in palm-foot sole), *Atisweda* (excess sweating), *Daurbalya* (weakness), and *Shrama* (fatigue), and significant relief was obtained in *Kara-Pada Tala Daha* (burning sensation in palm-foot sole), *Gala Talu Shosha* (dryness of mouth), and *Pindikodvestana* (leg cramps), while *Bhara Hani* (loss of weight) got insignificantly relieved. Whereas in group B, highly significant improvement was obtained in *Prabhuta Mutrata*, *Avila Mutrata* (turbid urine), *Kshudhadhikya*, *Trishadhikya*, *Kara-Pada Tala Daha*, *Kara-Pada Tala Suptata*, *Atisweda*, *Gala Talu Shosha*, *Daurbalya*, *Shrama*, *Pindikodvestana*, and *Bhara Hani*, with better percentage achieved in relief [Table 1].

In general, 60.52% in group A reported relief in all the symptoms, whereas in group B better relief (71.13%) was obtained.

On positive *Manasabhava*, insignificant improvement was recorded in *Harsha* (cheerfulness) and *Avasthana* (stability) in Group A. Whereas in Group B, highly significant improvement was recorded in *Harsha*, *Priti* (happiness), *Dhairya* (fearlessness), and *Avasthana*. Significant improvement was obtained in *Virya* (beginning of work) and *Shraddha* (good attitude), while insignificant improvement was recorded in *Dhriti* (good control) [Table 2].

On negative *Manasabhava*, highly significant decrease was noted in *Chinta* (worry), *Chittodvega* (anxiety), and *Upadhi* (impact). Significant relief obtained in *Krodha* (anger) and *Bhaya* (fear), while *Shoka* (sorrow), *Dvesha*, *Moha*, *Raga* (attachment), and *Udvega* were insignificantly relieved in group A. Whereas highly significant decrease was observed in *Chinta*, *Vishada*, *Krodha*, *Shoka*, *Bhaya*, *Upadhi*, *Udvega*, and *Chittodvega*, while *Mana* and *Raga* were insignificantly improved in group B [Table 3].

On all disturbed *Manasabhavas*, Group A demonstrated only 8.27% improvement, whereas Group B demonstrated 29.16% improvement.

On BPRS, Group A showed highly significant relief in fear of physical illness of somatic concern, worry and fear of anxiety, tension, and unusual thought content. Over concern for present or future of anxiety and thought process confusions of conceptual disorganization were significantly reduced. Where as Group B therapy showed highly significant relief in fear of physical illness of somatic concern; worry, fear, and over concern for present or future of anxiety; thought process confusions of conceptual disorganization; overactivation and tension; slow motor retardation; unusual thought content; and heightened emotional tone and increased reactivity of excitement. Strange thought content, reduced emotional tone, and reduction in normal intensity of feelings of blunted affect were significantly reduced [Table 4].

In all the parameters of BPRS, group A showed 14.59% relief while group B showed 38.28% relief.

In the hematological investigations, in both therapeutic groups, hemoglobin was insignificantly increased and erythrocyte sedimentation rate (ESR) was reduced insignificantly. In the lipid profile, serum triglyceride and VLDL were significantly decreased and serum cholesterol was insignificantly reduced, while HDL was insignificantly improved in Group A. In Group B, serum cholesterol and LDL were significantly decreased and serum triglyceride and VLDL reduced insignificantly, while HDL insignificantly increased. In the renal profile, serum creatinine and blood urea were increased in group A, whereas in group B serum creatinine was increased but blood urea was insignificantly decreased [Table 5].

Table 1: Effect on symptoms of type-II diabetics

Symptoms	Group A			Group B		
	No. of pts	% Relief	*P*	No. of pts	% Relief	*P*
Prabhuta mutrata (polyuria)	15	54.55	≤0.001	19	76.92	≤0.001
Avila mutrata (turbid urine)	2	66.67	-	4	83.33	-
Kshudhadhikya (polyphagia)	9	55.00	≤0.01	14	53.85	≤0.001
Trishadhikya (polydipsia)	13	46.88	≤0.01	14	47.83	≤0.001
Kara-pada tala daha (burning sensation in palm–foot)	5	50.00	-	12	47.83	≤0.001
Kara-pada tala suptata (numbness in palm–foot)	14	67.86	≤0.001	19	78.57	≤0.001
Atisweda (excessive sweating)	11	60.87	≤0.001	13	36.36	≤0.001
Gala talu shosha (dryness in mouth)	6	53.85	≤0.05	9	58.33	≤0.001
Daurbalya (weakness)	29	61.36	≤0.001	29	75.00	≤0.001
Shrama (fatigue)	24	59.32	≤0.001	31	70.37	≤0.001
Pindikodvestana (leg cramps)	17	59.62	≤0.001	21	71.19	≤0.001
Bharahani (loss of weight)	5	50.00	-	8	80.00	≤0.001
Mutre abhidhavanti pipilika	2	100.00	-	1	100.00	-

PPBS and urine sugar were significantly decreased and FBS was insignificantly reduced in Group A, whereas in Group B, FBS and PPBS were highly significantly decreased and urine sugar was insignificantly decreased with better percentage relief [Table 6].

Comparing the effects of both therapies on all symptoms with the statistical parameter χ^2, the result was found to be highly significant (11.96) [Figure 1]. χ^2 on all disturbed *Manasabhavas* was significant (6.58) [Figure 2]. Comparing the efficacies of both groups on BPRS, the effect of Group B was found to be significantly better on χ^2 (6.35) [Figure 3].

On comparison of efficacy in lowering the high blood sugar, the Group B was found to be better with high significance of χ^2 (9.68) [Figure 4].

Analysing the overall effect of therapy, 8.82% patients markedly improved, 38.24% moderately improved, 26.47% improved, and 26.47% patients remained unchanged in the Group A. Whereas in Group B, 32.35% patients markedly improved, 58.82% moderately improved, 8.82% improved, and none remained unchanged [Figure 5].

On comparison of overall therapeutic efficacy, only 16 patients of Group A showed improvement, whereas 31 patients in Group B improved, which illustrates that Group B was more effective with highly significant χ^2 (15.50) [Figure 6].

Table 2: Effect on disturbed positive *Manasabhava*

Manasabhava	Group A			Group B		
	No. of pts	% Relief	*P*	No. of pts	% Relief	*P*
Harsha (cheerfulness)	23	6.25	>0.05	24	25.53	≤0.01
Priti (happiness)	23	0.00	-	26	22.22	≤0.01
Dhairya (fearlessness)	24	0.00	-	30	30.77	≤0.001
Virya (beginning of work)	2	0.00	-	6	33.33	≤0.05
Avasthana (stability)	27	9.76	>0.05	29	33.33	≤0.001
Shraddha (good attitude)	8	0.00	-	15	14.29	≤0.05
Dhriti (good control)	3	0.00	-	4	20.00	>0.05

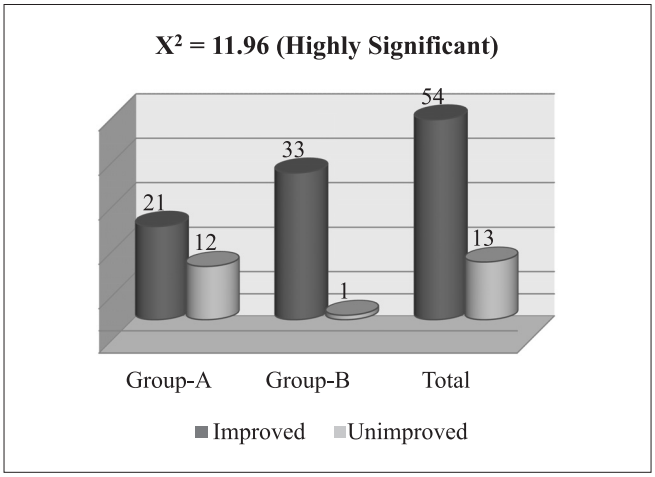

Figure 1: Comparison of therapies on symptoms with X^2

Discussion

The HMC is able to correct provoked *Dosha*, vitiated *Dushya*, hampered *Agni*, and affected *Srotas* involved in the pathophysiology of type-II DM by its potent ingredients. *Shilajatu* with its *Tikta Rasa* (bitter taste), *Katu Vipaka*, and *Lekhana* property decreases excess of *Kapha* and *Meda*, as well has a curative effect on disease of *Mutravaha Srotas*.[8] *Guggulu* with its *Tikta-Katu Rasa* and *Ushna Virya* reduces increased *Meda* and *Kapha* and pacifies *Vata*. *Triphala* with its *Kashaya Rasa*, *Laghu-Ruksha* property causes a decline in excess of *Sharira Kleda*, *Vasa*, and *Meda*.[9] *Vijaysara* with its *Tikta-Katu-Kashaya Rasa* and *Laghu-Ruksha* property diminishes excessive *Kapha*,[10] and *Saptarangi* with

Table 3: Effect on disturbed negative *Manasabhava*

Manasabhava	Group A			Group B		
	No. of pts	% Relief	*P*	No. of pts	% Relief	*P*
Chinta (worry)	34	18.27	≤0.001	34	49.50	≤0.001
Vishada (depressed mood)	22	0.00	-	28	38.30	≤0.001
Krodha (anger)	11	17.39	≤0.05	14	36.36	≤0.01
Shoka (sorrow)	10	9.52	>0.05	12	36.36	≤0.01
Bhaya (fear)	23	14.29	≤0.05	30	30.95	≤0.001
Mana (exaggerated confidence and self-esteem)	1	0.00	-	6	11.11	>0.05
Raga (attachment)	11	7.14	>0.05	13	5.88	>0.05
Upadhi (impact)	32	17.57	≤0.01	33	46.99	≤0.001
Udvega (apprehension)	28	4.65	>0.05	27	35.56	≤0.001
Chittodvega (anxiety)	28	13.89	≤0.001	31	46.05	≤0.001

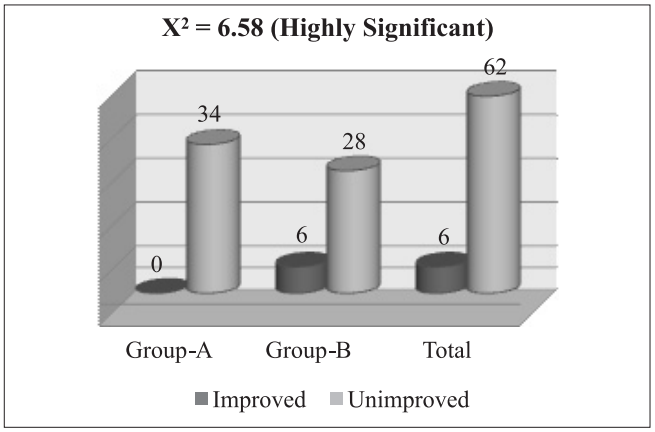

Figure 2: Comparison of therapies on *Manasabhava* with X^2

Table 4: Effect on brief psychiatric rating scale

	Group A			Group B		
	No. of pts	% Relief	*P*	No. of pts	% Relief	*P*
Somatic concern						
Fear of physical illness	20	25.00	≤0.001	28	54.72	≤0.001
Anxiety						
Worry	34	21.18	≤0.001	33	51.25	≤0.001
Fear	22	16.28	≤0.01	32	49.77	≤0.001
Over concern for present or future	13	30.77	≤0.05	16	41.94	≤0.001
Conceptual disorganization						
Thought process confusions	17	17.65	≤0.05	18	44.44	≤0.001
Guilt feelings						
Self-blame	1	0.00	-	2	50.00	-
Shame	0	-	-	2	50.00	-
Tension						
Physical/motor manifestations or nervousness	3	14.29	>0.05	4	25.00	>0.05
Over activation	17	8.70	>0.05	24	39.02	≤0.001
Tension	33	24.66	≤0.001	33	45.00	≤0.001
Motor retardation						
Slowed	10	10.00	>0.05	8	18.18	<0.001
Weakened movements or speech	7	0.00	0.00	5	16.67	-
Reduced body tonic	4	0.00	-	4	25.00	-
Uncooperativeness						
Resistance	6	0.00	0.00	10	26.67	≤0.05
Unusual thought content						
Unusual thought content	26	17.74	≤0.01	29	50.00	≤0.001
Strange thought content	8	8.33	>0.05	10	28.57	≤0.05
Blunted affect						
Reduced emotional tone	12	6.25	>0.05	14	13.64	≤0.05
Reduction in normal intensity of feelings	11	6.67	>0.05	10	21.43	≤0.05
Flatness	1	0.00	-	3	25.00	>0.05
Excitement						
Heightened emotional tone	7	18.18	>0.05	14	38.46	≤0.001
Agitation	3	0.00	-	4	33.33	-
Increased reactivity	7	12.50	>0.05	15	33.33	≤0.01

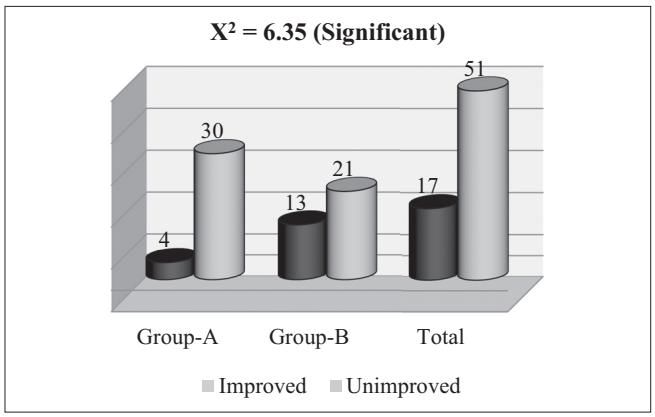

Figure 3: Comparison of therapies on BPRS with X^2

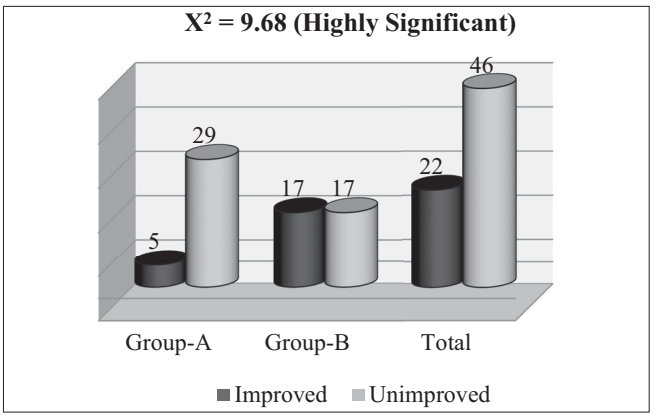

Figure 4: Comparison of therapies on blood sugar with X^2

its *Kashaya-Tikta Rasa* and *Laghu-Ruksha* property not only decreases *Kapha* and *Pitta*, but also improves *Rakta*.[11] The *Rasayana* effect of *Shilajatu*, *Guggulu*, and *Triphala* improves all *Dhatus* and provides relief in *Dhatukshayatva* and *Ojokshayatva* of disease.[12] Hence, significant relief was obtained with HMC. Diabetes, being a psychosomatic disease, both *Sharirika* and

Table 5: Effect on biochemical investigations

	Group A			Group B		
	No. of pts	% Relief	*P*	No. of pts	% Relief	*P*
Hemoglobin	34	1.39	>0.05	34	2.46	>0.05
ESR	34	−3.69	>0.05	34	17.60	>0.05
Lipid profile						
Sr. cholesterol	32	1.13	>0.05	32	5.51	≤0.05
Sr. triglyceride	34	10.82	≤0.05	33	1.64	>0.05
HDL	32	1.49	>0.05	32	9.65	>0.05
LDL	32	−1.06	>0.05	32	10.72	≤0.05
VLDL	34	10.82	≤0.05	33	1.64	>0.05
Renal profile						
Sr. creatinine	34	−2.13	>0.05	34	−0.87	>0.05
Blood urea	34	−10.20	>0.05	34	0.94	>0.05

ESR-Erythrocyte sedimentation rate; HDL-High density lipoprotein; LDL-Low density lipoprotein; VLDL-Very low density lipoprotein

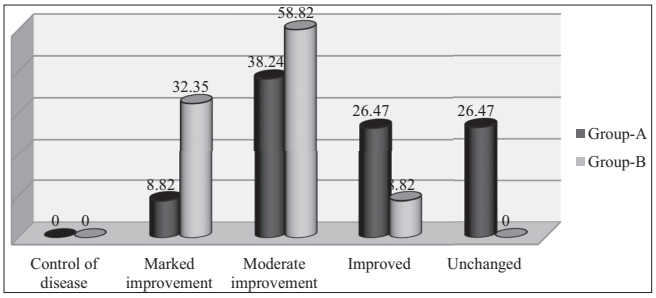

Figure 5: Over all effect of therapy

Table 6: Effect on blood sugar and urine sugar

	Mean score		% Relief	SD (±)	SE (±)	"*t*"	*P*
	BT	AT					
Group A							
FBS	162.00	155.44	4.05	31.38	5.38	1.22	>0.05
PPBS	242.32	218.21	9.95	71.45	12.25	1.97	≤0.05
US	0.74	0.41	44.00	0/73	0.12	2.59	≤0.05
Group B							
FBS	202.76	166.18	18.04	41.67	7.52	5.12	≤0.001
PPBS	278.47	201.21	27.75	63.84	10.95	7.06	≤0.001
US	0.79	0.59	25.93	0.95	0.16	1.27	>0.05

FBS-Fasting blood sugar; PPBS-Post prandial bolld sugar; US-Urine sugar

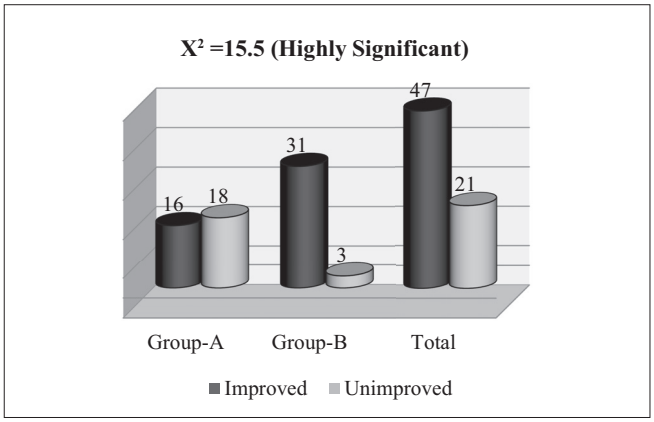

Figure 6: Comparison of therapies on over all effect with X^2

Manasika Dosha are vitiated and affect each other mutually[13] as sorrow and fear provoke *Vata* and anger provokes *Pitta*.[14] *Medhya* drug calms the mind and normalizes vitiated *Manasa Dosha*, which subsequently improves vitiation of *Sharirika Dosha* and related symptoms. Therefore, MR-*Shankhapushpi*, when added to principal therapy HMC, provided better relief in symptoms with highly significant result on χ^2 (11.96).

The root cause of disturbance of psychological factors is various types of *Ichchha*, i.e., desire, and *Dvesha*, i.e., hatred.[15] When one cannot get the desired thing or one gets unwanted thing, it produces stress,[16] causing disturbance of positive psychological and negative psychological factors leading to vitiation of *Raja* and *Tama*. Due to these, *Manasa Vikaras* are produced.[17] When *Shankhapushpi* with proven stress relieving psychotropic effect in experimental rats[18,19] was administered, it improved the disturbed psychological factors and re-established the balance of *Rajas* and *Tamas*. That's why, HMC + MR therapy (29.16%) was significantly better than single administration of HMC (8.27%) on χ^2 (6.58) to improve disturbed *Manasabhava*.

The pharmacological studies proved that *Shankhapushpi* enhances neuropeptide synthesis in the brain. Moreover, it reduces the level of acetylcholine and catecholamine in the brain tissue,[20] which are elevated because of disturbed psychological factors. This way *Shankhapushpi* as an MR provides psycho-stimulant and psycho-tranquilizer effects in animal experiments.[21] In clinical study also, it had shown significant anxiety relieving results.[22] That's why when *Shankhapushpi* was administered along with HMC, better results (χ^2 = 6.35) were obtained in BPRS adopted for evaluating the improvement in psychological factors.

Hemoglobin and ESR were within normal limits in both the groups before treatment and remained normal after completion of therapy. The slight increase noted in hemoglobin was due to hemoglobin increasing effect of *Amalaki*[23] and *Shilajatu*.[24] The ESR came down slightly due to anti-infective activities of *Guggulu*.[25]

In diabetic patients of both therapeutic groups, the mean scores of lipid profile were within the physiological range. Also, most of the patients had normal lipid profile before and after treatment. Therefore, it was obvious to obtain insignificant results for lipid profile in both the groups, although positive effect was noticed in those diabetic patients whose lipid profile was abnormally high. The contents of HMC-*Triphala*,[26] *Shilajatu*,[27] and *Guggulu*[28] -have *Medohara*/antihyperlipidemic effect. That's why antihyperlipidemic action was seen in the present study. Similarly in the renal profile, the mean scores of serum creatinine and blood urea were increased or decreased within their physiological range by therapy.

The main diagnostic object of diabetes is elevated blood sugar, which came down by clinically proven ingredients of HMC. *Shilajatu* is effective in controlling the blood glucose level by its fulvic acid.[26] Oral administration of the extracts of *Triphala* significantly reduced the blood sugar level in normal and in alloxan diabetic rats.[29] Pterostilbene, marsupsin, and epicatechin present in the bark of *Vijaysara* are reported to significantly lower the blood glucose and reverse the damage

of β-cells.[30,31] *Saptarangi* showed potent antihyperglycemic effects.[32] The impulses of disturbed psychological factors release epinephrine and norepinephrine, which increase glycogenolysis and lipolysis. Furthermore, stress and tension increases the level of neurotransmitters like catecholamines, epinephrine and norepinephrine, which work as an insulin antagonist.[33] When mental health promoting MR was administered together with HMC to normalize the disturbed psychological factors, it takes better care of neuroendocrine changes related to insulin antagonism.[33] Therefore, HMC + MR showed better relief on high blood sugar ($\chi^2 = 9.68$).

In nutshell, HMC improved the symptoms and elevated blood sugar, but it did not have significant effect on disturbed *Manasabhava*-induced pathophysiology of *Madhumeha*. So, when *Shankhapushpi*, having *Medhakrita*, *Medhya*, *Smruti Vardhak*, and *Manasarogahara* effects,[34,35] was administered along with the antidiabetic HMC, it showed better improvement in the overall health including relief in symptoms (group A = 60.52%, group B = 71.13%), decrease in high blood sugar (group A = 4.48%, group B = 21.13%), and improvement in mental health based on BPRS (group A = 14.59%, group B = 38.28%) and *Manasabhava* (group A = 8.27%, group B = 29.16%).

On overall effect of therapy, more patients showed marked (group A = 8.82%, group B =32.35%) or moderate improvement (group A = 38.24%, group B =58.82%), whereas less patients were under the category of unchanged (group A = 26.47%, group B = 00%) or improved (group A = 32.35%, group B = 8.82%) in HMC + MR-*Shankhapushpi* group. Furthermore, it was proved by statistical parameter χ^2 (15.50) with a high significance, which showed that combined therapy improved the patients in a more pronounced manner.

Conclusion

Stress plays an important role in the etiopathogenesis of type-II DM, which is well comparable to *Avaranajanya Madhumeha*. Though the disease is *Tridoshik* in nature, in the initial stage there is dominancy of *Kapha (Bahudrava Sleshma)* followed by *Pitta* and *Vata* in association with *Dushya* at various levels. All these changes lead to hyperglycemia, imbalance lipid profile with high level of catecholamine and other insulin antagonists. The trial drug HMC has antipyperglycemic/hypoglycemic and hypolipidemic properties is a drug of choice for *Samprapti Vighatana* of disease. Simultaneous administration of *Medhya* drug like *Shankhapushpi* has further potentiated the therapeutic efficacy of the principal antidiabetic compound by counteracting stress and due to its antioxidant and immunomodulatory properties.

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हिन्दी सारांश

हर्बो–मिनरल कंपाउण्ड के साथ मेध्य रसायन का टाइप – २ डायाबिटिस पर प्रभावात्मक अध्ययन

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विश्व स्वास्थ्य संगठन के अनुसार डायाबिटिस की व्यापकता बढ़ने के मुख्य कारणों में से एक है, दिन–प्रतिदिन का तनाव, जो सकारात्मक और नकारात्मक मानसभावों के संतुलन को विचलित करके डायाबिटिस जैसी मनो–शारीरिक व्याधि उत्पन्न करता है । इस तथ्य को ध्यान में रखते हुए टाइप – २ डायाबिटिस में व्याधिहर हर्बो–मिनरल कंपाउण्ड (शिलाजीत, गुग्गुलु, विजयसार घन, त्रिफला घन, सप्तरंगी घन) के साथ मेध्य रसायन (शंखपुष्पी) की चिकित्सकीय भूमिका का अध्ययन किया गया । इस शोधकार्य के प्रथम वर्ग के ४८ रूग्णों में हर्बो–मिनरल कंपाउण्ड ३ ग्राम प्रतिदिन तीन विभाजित मात्रा में ८ सप्ताह तक सुखोष्ण जल से भोजन पूर्व देने पर अभुक्त शर्करा में ४.०५% एवं भोजनोत्तर शर्करा के स्तर में ९.९५% की कमी हुई । जबकि दूसरे वर्ग के ४५ रूग्णों में हर्बो–मिनरल कंपाउण्ड की उपरोक्त मात्रा के साथ–साथ मेध्य रसायन शंखपुष्पी १.५ ग्राम/प्रतिदिन तीन विभाजित मात्रा में ८ सप्ताह के प्रयोग से अभुक्त शर्करा में १८.०४% और भोजनोत्तर शर्करा के स्तर में २७.७५% की कमी पाई गई । लाक्षणिक सुधार के साथ–साथ विचलित मानसभाव और ब्रिफ सायकायट्री रेटिंग स्केल पर भी सुधार देखा गया । उक्त दोनों वर्गों के परिणामों का सांख्यकीय विश्लेषण (X^2) करने पर पाया गया कि हर्बो–मिनरल कंपाउण्ड के साथ मेध्य रसायन का टाइप–२ डायाबिटिस पर प्रयोग तुलनात्मक रूप से अत्यधिक प्रभावशाली रहा ।