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Original Research Article

Clinical appraisal of Lodhradi Kashaya on type 2 diabetes mellitus patients

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ABSTRACT

Background: Lodhradi Kashaya (LKSD) is basically ayurvedic kwath dosage form, described as Madhumehajeet (winner of diabetes mellitus) in ayurvedic classics Basavarajeeyam and the same formulation in Vaidya Chintamani and Charaka Samhita too. The aim of this study was to assess prospectively the drug's ability in management of type 2 diabetes.
Methods: Total 31 patients were taken following the guideline mention in CCRAS protocol for diabetes mellitus research. They are divided into two groups, group A and B, given LKSD 4 g & 2 g TDS respectively for three-month follow up. They are investigated against their blood glucose, HbA1C and liver profile tests. Patients were also investigated for subjective parameters viz polyurea, polyphagia, exhaustion and constipation and their response has also been noted regarding palatability acceptance and ease of administration.
Results: Patients has responded positively for formulation. Decrease in FBS and PPBS were found highly significant ($P < 0.001$) in both groups but more in higher dose (group A). Decrease in HbA1C is also found highly significant in both groups. In LFT, SGOT level were also decreased more in group B in comparison to group A, and it is significant ($P = 0.017$ and 0.002). SGPT level were also decreased more in group B in comparison to group A, and it is significant in group B ($P= 0.085$ and 0.002).
Conclusions: LKSD is having astringent taste due to tannins and phenols in it. It was found significant not only in controlling blood sugar but also in management of other factors related to diabetes mellitus.

Keywords: Ayurveda, Lodhradi Kashaya, Diabetes mellitus, Clinical study

INTRODUCTION

Diabetes is not the disease of 19-21st century, but it was known since ancient times in the name of Prameha with synonyms of madudhatu, madhuprameha, ojomeha, kshoudrameha. Types and symptom along with management approach was discussed and dictated in ancient texts elaboratly. Madhumeha can be considered as diabetes mellitus (DM) by different perspectives based on clinical symptoms and attempts have been made by ayurvedic physicians and researchers to treat these two entities by using classical formulations mentioned in Prameha Chikitsa.[1] DM is not a single disease but it is a metabolic-cum-vascular syndrome of multiple aetiologies characterise by chronic hyperglycaemia with distribution of carbohydrates, fats, protein metabolism resulting from defect in insulin secretion or insulin action or both. The chronic hyperglycaemia of diabetes is associated with long term damage, dysfunction, and failure of various organs due to malfunctioning of bio-physiology.[2] World is standing over diabetic bomb as in 2014 the global prevalence of diabetes was estimated to be 9% among adults. In 2012, an estimated 1.5 million deaths were directly caused by diabetes and among them cardiovascular disease is responsible for between 50% and 80% of deaths in people. About 347 million people

worldwide have diabetes, among them 90% have DM.[3] WHO (World Health Organization) runs many program for diabetic awareness but still people have thought that only blood glucose level is area of concern for diabetes mellitus while it is wrong because blood glucose is symptom that our body physiology is started malfunctioning. We found that diabetes is described since before 1000 BC in the name of Prameha (diabetes) in Ayurveda. Prameha is elaborately described and discussed with their types, symptom and management by specific formulations as well as life styles. It is surprising that ancient scholars had prime focus to treat disease along with management of complications and thus use multi ingredient therapy for madhumeha (diabetes mellitus). They use multi drugs formulation having ingredient based on treatment approach to type of diabetes, prakriti (body constitution that may be co related with genomic constitution) and possible complication that may arise in future. A report quote, nearly 22% of people with diabetes in the USA use herbal therapy and about 31% use dietary supplements for controlling blood sugar level and related complications.[4]

Lodhradi Kashaya is basically described as ayurvedic kwath dosage form (decoction) in Basavarajiyam (Kaphaj Prameha), Meharoga Nidan Lakshanam Chikitsadhyaya and here it was called as Madhumehajeet (win over diabetes) when administered with honey.[5] The formulation having same ingredients as given in Table 1 was also mentioned in Vaidya Chintamani under 'Prameha Prakaranam' as well as in Charaka Samhita for the treatment of Kaphaja Prameha.[6] So this formulation has been selected for study and its ingredients were kept under investigation on account for their properties to correlate with contemporary science.

Table 1: Ingredients of Lodhradi Kashaya.

Serial	Plant	Botanical name	Family	Part used	Ratio
1.	*Lodhra*	*Symplocos racemosa* Roxb.	Symplocaceae	Stem bark	1 part
2.	*Hareetaki*	*Terminalia chebula* Retz.	Combretaceae	Fruit pulp	1 part
3.	*Musta*	*Cyperus rotundus* Linn.	Cyperaceae	Rhizome	1 part
4.	*Katphala*	*Myrica esculenta* Linn.	Myricaceae	Stem bark	1part

METHODS

Study design

Total 36 patients were registered for clinical trial at OPD of department of Rasa Shastra, Indian medicine wing, Sir Sunder Lal Hospital, Banaras Hindu University, Varanasi in which 5 patients were dropped out. Inclusion criteria for selection of patients was either sex, age group of 30 – 70 years, 8 hour fasting blood sugar (FBS) >126 and < 250 mg/dl and 2 hour postprandial blood sugar (PPBS) >200 to <= 350 mg/dl. We exclude the patients not lying in parameter of inclusion criteria and patients suffering from retinopathy, nephropathy, cardiovascular problems, hormonal imbalance, regnant and lactating mother. Their blood sugar (FBS and PPBS) has been investigated at starting, after one month, two months and after 3 months while HbA1C, SGOT, SGPT, and creatinine has been investigated at starting and end of the study (3 month). We have followed the protocol for diabetes mellitus published by CCRAS.[7] This clinical study has been registered in Institutional Ethical Committee, Institute of Medical Sciences, Banaras Hindu University as 'ECR/526/Inst./UP/2014'. This study has been registered under CTRI as CTRI/2016/09/007243. Patients were also questioned for astringency of taste, acceptability, other related problems like constipation, exhaustion, polydipsia etc.

Trial drugs

For this study, Lodhradi Kashaya spray dried powder (LKSD) has been made available to patients by modifying the kashaya (decoction) form into powder dosage form, using spray drier technology at Sanath Products Ltd., Sikandarabad, Noida, UP.[8] In order to maintain its principle administrable form as kashaya, it was recommended to dissolve unit dose into luke warm water to make in to kashaya form.

Patients grouping

Total 31 patients were divided into two groups, group A and group B having 14 patients and 17 patients respectively. Group A (patients having fasting blood sugar more than 160) was given a dose of 4 g TDS while group B (patients having fasting blood sugar less than 160) was given 2 g TDS of LKSD. The patients were strictly advised to dissolve suitable quantity of powder into 100 ml luke warm water just before administration and drink it. Patients are advised to do regular exercise and diet control as prescribed to avoid high sugar content diet. Patients are also advised to examine blood sugar on regular interval and council to take Lodhradi Kashaya in proper manner.

Statistical analysis

Findings were analyzed statistically by SPSS 16.00 version applying the paired t-test, one-way ANOVA, Friedman test and Chi square test. The results are interpreted with possible co relation of ayurvedic and contemporary point of view. $P < 0.05$ was considered statistically significant and $p < 0.001$ were considered highly significant in the results of this study.

RESULT

All the patients were selected independently of their sex, age, caste, economy and religions. Total 36 patients were registered while 5 have left the study due to their own consent. Patient's variable and their profile were given in Table 2.

Patients were also investigated against their subjective parameters like polyurea, polyphagia, exhaustion feeling of patients and constipation as shown in Table 3-6. All the parameters were accessed by oral assessment of patients by questioner. Very less patients have complaint about polyurea and polyphagia while reported patients claiming for improved status. There is significant improvement in case of exhaustion of patients. In case of constipation, this formulation shows highly significant effect and makes patients feel good.

Table 2: Patients distribution and variables.

Patients variables	Division of variables	Group A (% of patients)	Group B (% of patients)
No. of patients	Total	14	17
Age Group	30-40 years	7.10	17.64
	41-50 years	28.57	29.41
	51-60 years	35.71	29.41
	61-70 years	28.57	23.52
Sex	Male	100	82.2
	Female	0	11.8
Diabetic family history	Yes	28.10	17.6
	No	71.6	82.4
Diet	Vegetarian	57.1	29.4
	Mixed	42.9	70.6
Addiction	Tobacco	35.7	11.8
	Smoking	14.3	0
	Alcohol	7.1	0
BMI	(≤ 18)	0	0
	(≥18 to ≤24.9)	21.42	41.17
	≥ 25	78.57	58.82
Review on astringency of Lodhradi Kashaya	0	0	0
	1	7.1	0
	2	42.9	47.1
	3	50	51.6

Table 3: Effect of Lodhradi Kashaya in polyuria.

Groups	Grade	Polyurea (Number of cases)				Within the group comparison Friedman test
		0 Days	30 Days	60 Days	90 Days	
A	**0**	11	11	12	12	X^2 =4.71 P=0.194
	1	2	3	2	2	
	2	1	0	0	0	
	3	0	0	0	0	
B	**0**	14	15	15	15	X^2 =3.000 P=0.392
	1	1	2	2	2	
	2	1	0	0	0	
	3	1	0	0	0	
Within the group comparison Chi square test		X^2 =0.562 P=0.755	X^2 =0.530 P=0.403	X^2 =0.043 P=0.835	X^2 =0.043 P=0.835	

Table 4: Effect of Lodhradi Kashaya on polyphagia.

Groups	Grade	Polyphagia (Number of cases)				Within the group comparison Friedman test
		0 Days	30 Days	60 Days	90 Days	
A	**0**	12	13	13	13	X^2 =1.00 P= 0.801
	1	1	1	1	1	
	2	1	0	0	0	
	3	0	0	0	0	
B	**0**	17	17	17	17	X^2 =000 NA
	1	0	0	0	0	
	2	0	0	0	0	
	3	0	0	0	0	
Within the group comparison Chi square test		X^2 =2.596 P=0.273	X^2 =1.255 P=0.283	X^2 =1.255 P=0.283	X^2 =1.255 P=0.283	

Table 5: Effect of Lodhradi Kashaya on exhaustion feelings of patient.

Groups	Grade	Exhaustion (Number of cases)				Within the group comparison Friedman test
		0 Days	30 Days	60 Days	90 Days	
A	**0**	6	7	7	7	X^2 =13.68 P= 0.003
	1	2	4	6	6	
	2	4	3	1	1	
	3	2	0	0	0	
B	**0**	10	11	14	14	X^2 =13.036 P= 0.005
	1	3	5	2	3	
	2	3	1	1	0	
	3	1	0	0	0	
Within the group comparison Chi square test		X^2 =1.399 P=0.706	X^2 =1.726 P=0.422	X^2 =4.081 P=0.130	X^2 =4.081 P=0.130	

Table 6: Effect of Lodhradi Kashaya on constipation.

Groups	Grade	Constipation (Number of cases)				Within the group comparison Friedman test
		0 Days	30 Days	60 Days	90 Days	
A	**0**	4	9	9	10	X^2 =23.174 P< 0.001
	1	4	4	4	4	
	2	3	1	1	0	
	3	3	0	0	0	
B	**0**	8	11	12	12	X^2 =18.559 P< 0.001
	1	2	2	2	3	
	2	4	3	2	1	
	3	3	1	1	1	
Within the group comparison Chi square test		X^2 =1.870 P=0.600	X^2 = 2.601 P=0.457	X^2 =2.158 P=0.540	X^2 =2.054 P=0.561	

Patients were investigated for objective parameters, blood sugar level (fasting and postprandial), HbA1C and LFT (SGOT, SGPT) and creatinine as given in Table 8. Effect of Lodhradi Kashaya was found highly significant in case of fasting blood sugar as well as postprandial blood sugar in group A and group B as given in Table 7. Among them group A shows more significant in comparison to group B in both the cases.

Effect of Lodhradi kashaya were also investigated for Glycated hemoglobin (hemoglobin A1c), and showed significant decrease in both group, A & B as given in Table 8. In LFT profile, SGOT was analyzed for both groups, it was reduced significantly as shown in Table 8. SGPT was also screened at starting and end of the study and it was reduced significantly in group B while no significant decreased in group A as in Table 8.

Table 7: Effect of Lodhradi Kashaya on blood sugar (fasting and postprandial).

Groups	Fasting Blood Sugar (Mean ± SD)				Postprandial Blood Sugar (Mean ± SD)			
	0 day	**30 days**	**60 days**	**90 days**	**0 days**	**30 days**	**60 days**	**90 days**
A	175.93 ± 12.12	162.21 ± 14.66	142.07 ± 14.38	134.50 ± 12.30	291.50 ± 51.12	216.50 ± 49.16	192.07 ± 34.12	177.50 ± 21.84
B	135.59 ± 8.76	120.70 ± 8.06	115.41 ± 8.32	115.41 ± 8.86	230.82 ± 26.09	170.82 ±26.99	157.76 ± 24.11	144.53 ± 18.31
Within the group comparison Paired t test BT-AT	For Group A 41.42 ± 18.44 t= 8.403 P < 0.001		For Group B 20.17 ± 7.22 t= 11.51 P < 0.001		For Group A 114.00 ± 34.90 t= 12.22 P < 0.001		For Group B 86.29 ± 17.20 t= 20.68 P < 0.001	

Table 8: Effect of Lodhradi Kashaya on HbA1C, SGOT, SGPT and creatinine.

Group	Mean ± SD							
	HbA1C		**SGOT**		**SGPT**		**Serum Creatinine**	
	0 Day	90 Days	0 Day	90 Days	0 Day	90 Days	0 Day	90 Days
A	8.52 ± 1.46	7.07 ± 0.60	28.42 ± 10.56	24.12 ± 8.11	33.63 ± 9.79	29.35 ± 8.16	0.89 ± 0.11	0.72 ± 0.10
B	7.67 ± 0.89	6.77 ± 0.48	28.62 ± 7.99	25.55 ± 6.43	38.73 ± 12.82	32.68 ± 9.62	0.93 ± 0.15	0.85 ± 0.12

DISCUSSION

Herbal medicines have great demand in the developed and developing countries for primary healthcare because of their wide biological and medicinal activities, higher safety margins, consumer own interest and reasonable cost. Here a formulation which was shown in Table1 having natural ingredients was selected from arena of Ayurvedic wisdom as it was dictated as 'Madhumehajeet (winner of DM)' in Basavarajeeyam and same formulation also in Vaidya Chintamani and Charaka Samhita too. This formulation was indicated to take as kashaya form so here we made an attempt to dissolve the kashaya powder into luke warm water just before administration so that we can stick to fundamental prescribed dosage form while validating the ancient wisdom. Kashaya was indicated to take in 2 pala (Sharangdhar Samhita) or 1 pala (Yadav ji Tikkam Ji) in divided dose while in API (The Ayurvedic Pharmacopoeia of India) suggest to take kashaya from 48 g of kwath churna. If we make kwath and dry it, then we gat yield of about 12 g/6 g in a day. So on this basis two dose i.e. 4 g TDS and 2 g TDS dose has been decided for human being. Patients were grouped into A (FBS ≥ 160) and B (FBS < 160) were given treatment with 4 g TDS and 2 g TDS respectively. Ayurveda also have upper hand in recognition of prediabetic stage described in ayurvedic science like knotted hair, burning sensation, numbness, sweetness in mouth, laziness, body odour like fish whereas modern science has no such criteria. DM is due to increase in vata caused by either blockage of strota (body channel) by aggravated kapha and medo dhatu or due to mental stress, food habit, life style etc.[9] So ancient wisdom always talks about management of disease not only targeting the hypoglycemic action but also use the additive drugs in formulation to manage other possible complication or problems in future.

In clinical study, the patients were showed improvement of the subjective clinical symptoms i.e. polyurea, polyphagia, exhaustion/tiredness and constipation. The comparison done with respect to the all clinical symptoms, patients showed that both groups having significant improved in case of exhaustion feeling of patients and constipation after intervention has given as shown in Table 5 and 6. Patients were also investigated against their subjective parameters like polyurea polyphagia as in Table 3 and 4. All the parameters were accessed by oral assessment of patients by questioner. Very less patients have complaint about polyurea and polyphagia, and the reported patients showed improved status. There is significant improvement in case of exhaustion of patients but group A is more significant to group B (P= 0.003 and P= 0.005). Plants are having many of phytoconstituents like glycosides, tannins and polyphenols that are hypolipidemic in their action. They are also reported for their antioxidant activity thus they play major role in reducing exhaustion. In case of constipation, this formulation shows highly significant effect (P < 0.001) for both the groups among them group A patients showed better response. Anthroquinone and sennosides present in Haritaki are reported for strong purgative property thus this formulation is help in relieving from constipation.[10,11] In clinical assessment, FBS and PPBS both were decreased due to the effect of Lodhradi Kashaya. It was found highly significant in case

of fasting blood sugar ($P < 0.001$) as well as PPBS ($P < 0.001$) as given in Table 7, 8 in group A and group B. Among them group A shows more significant ($t= 8.403$, $P < 0.001$) in comparison to group B ($t= 11.51$, $P < 0.001$) for FBS. Currently, HbA1c test has been recommended for screening and diagnosis of diabetes.[12] The use of A1c may offer some advantages such as sampling at convenient time, no need for overnight fasting or availability of 75 g glucose and providing a measure of hyperglycemia over a prolonged duration, which are the major limitations of FPG or the OGTT. In addition, the result is unaffected and has a low biological variability and better pre-analytic stability.[13] Effect of Lodhradi Kashaya on glycated hemoglobin (hemoglobin A1c) was found significant in both group, A & B as given in Table 8. The hypoglycemic activity is mainly due to the phytoconstituents presents in the ingredients of Lodhradi Kashaya. All the ingredients are separately reported for their hypoglycemic action. Lodhra is reported for hypoglycemic and suggested that *Symplocos racemosa Roxb* might exert insulin-like effect on peripheral tissues by either promoting glucose uptake metabolism by inhibiting hepatic gluconeogenesis or by absorption of glucose into the muscle and adipose tissues.[14-16] It also acts through the stimulation of a regeneration process and revitalization of the remaining beta cells.[17,18] Ethanolic extract of Musta reported for hypoglycemic action by inhibiting intestinal glucose absorption and promoting glucose consumption.[19,20] Katphala was also reported for lowering blood glucose level.[21,22] Haritaki are well known for their hypoglycemic action.[23,24]

In LFT profile, SGOT was analyzed for both groups, it showed significant decrease as given in Table 8, which indicate that Lodhradi kashaya act as hepatoprotective as well as revitalizer for liver cell and its metabolic reactions. SGPT was also reduced significantly in group B while no significant decreased found in group A as given in Table 8. Hepatoprotective action has also been reported for its ingredients *Lodhra*, *Haritaki*, *Must* through their several mechanism of action.[25-28] So it can be concluded that Lodhradi Kashaya is not only beneficial in managing blood sugar level but also it is helpful in managing LFT and symptomatic problems like tiredness and constipation.

CONCLUSION

Lodhradi Kashaya is beautiful combination having four ingredients that were well reported for antidiabetic and hepatoprotective action through different mechanism of action in contemporary sciences. This formulation was mentioned century years before in Charaka Samhita, Vaidya Chintamani and Basavarajeeyam for management of Prameha. In present study, by clinical investigation we revalidate the therapeutic efficacy of Lodhradi Kashaya as 'Madhumehajeet' because it was highly significant in reducing FBS and PPBS. Also it was found significant effect in LFT. LKSD was also significantly effective in subjective clinical symptom like constipation and tiredness in addition to some effect in polyurea too. So we can cite that Lodhradi Kashaya is highly significant in management of type 2 diabetes mellitus.

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