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Research Article

CLINICAL EVALUATION OF MEDOUJA-DUSTI IN PRAMEHA WITH SPECIAL REFERENCE TO SERUM LIPOPROTEIN A LEVEL IN T2DM

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ABSTRACT

Dyslipidemia in type II diabetes mellitus in term of meda dusti in prameha also introduces Medouja-dusti. Due to faulty lipid metabolism, serum Lipoprotein A gets increased which can be interpreted as Medouja-dusti. The rationale of this study was to detect Medouja-dusti and medadusti in the patients of prameha in terms of serum Lipoprotein A along with lipid profile evaluating the efficacy of pippali churna. This study was a prospective, randomised and control clinical study having 2 groups, 30 patients each; group A (experimental) was treated with Pippali and group B (control) with Haridra. Patients were selected from OPD and IPD of- Institute Of Post Graduate Ayurvedic Education and Research at Shyamadas Vaidya Shastra Peeth Hospital, Kolkata, irrespective of sex and religion as per subjective criteria of prameha, Oja visramsa and oja vyapat and objective criteria of FBS, PPBS, HbA_1C, serum triglyceride, total cholesterol and Lipoprotein A following exclusion and inclusion criteria. Pippali churna had been administered orally at a dose of 3 gm/day at divided doses. Before and after treatment data had been assessed statistically. Group A had showed highly significant results ($p < 0.001$) in all the objective parameters where group B had showed result as highly significant ($p < 0.001$) in FBS, PPBS, Total Cholesterol and TG, significant ($p < 0.1$) in HbA_1C and non-significant in Lipoprotein A. Improvement of subjective criteria and unpaired 't' test proved group A as highly significant. Pippali reduced the lipids along with lipoprotein A simultaneously normalising blood sugar by its Rasapanchaka proving itself as an excellent remedy medadusti and Medouja-dusti in prameha.

Keywords: Dyslipidemia**,** medadusti, Medouja-dusti, prameha, serum Lipoprotein A, Pippali, type II Diabetes mellitus

INTRODUCTION

Diabetes mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycaemia. The features including its fate resemble with the vyadhi prameha in general. In the recent years, it has been found that Diabetes Mellitus is an ailment which is crippling the society day by day. Commonly in the clinics a large population presents Diabetes Mellitus associated with hyperlipidaemia. Prevalence of Diabetes Mellitus throughout the world has been reported- 8.5% as per report of 2014, which is in India- 7% adults with higher prevalence of males (7.1%) than females (6.8%). We can observe its prevalence in urban life (9.8%) than rural residents (5.7%)[1]. Diabetes Mellitus is a major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation, where hyperlipidaemia plays a major role in these complications. Causes of hyperlipidaemia in Diabetes Mellitus are still under probe of hypothesis. But it could be stated grossly that altered blood glucose level leads to defective fat metabolism at cellular level. Diabetes Mellitus can be correlated with prameha. Classically it is mentioned that Bahudrava kapha and Bahuabaddha meda are the main causative factors in pathogenesis of prameha[2]. But it has been significantly noted that oja dushti simultaneously happens with dhatu Kshaya in later stage[3]. As a result, levels of various lipids along with lipoproteins also become altered due to faulty fat metabolism in diabetic patients. Oja is the quintessence of all dhatus and responsible for vital strength of the body and resists against the disease[4]. The defence mechanism present in the body allows us to survive potentially against the hostile world of disease. Vyadhikshamatva is interpreted as vyadhibalavirodhitwa. The term vyadhikshamatva represents the bala and oja in the body[5]. Like other Ojas medouja also gets altered along with medadusti in prameha[6]. Hence, medouja dushti is a very essential factor in pathogenesis of Prameha. The rationale of this study was to detect Medouja-dusti along with medadusti in the patients of prameha in terms of serum Lipoprotein A along with serum triglyceride and serum total cholesterol and to evaluate the efficacy of *Piper longum* Linn. fruit powder in these subjects.

Aims and objectives

- To study the diagnostic approach of medouja.
- To evaluate the role of medouja in pathogenesis of prameha.
- To reveal the efficacy of pippali in Medouja dushti as well as prameha.

MATERIAL AND METHODS

Selection of the Subject

Patients were selected as known diabetic from OPD and IPD of the institute- Institute Of Post Graduate Ayurvedic Education and

Research at Shyamadas Vaidya Shastra Peeth Hospital, Kolkata, according to the blood glucose level, FBS and PPBS not exceeding 200 mg/dL and 300 mg/dL. After taking the detailed history, the consent was taken from each of the subjects and study was in accordance with ICH-GCP guidelines. Ethical clearance for the study has been obtained from Institutional ethical committee of Institute of Post Graduate Ayurvedic Education and Research at Shyamadas Vaidya Shastra Peeth Hospital, Kolkata, (SVP/558/2017 dated on 29.05.2017). The subjective criteria of Prameha, oja visramsa and oja vyapat are verified on those patients and the objective criteria of FBS, PPBS, HbA_1C, serum triglyceride, serum total cholesterol and serum Lipoprotein A have been assessed on them to search out medouja dushti along with medadusti. Subjective and objective criteria had been analysed clinically and statistically to evaluate the efficacy of pippali both in prameha and Medouja-dusti.

Sample Size and Sample Design

The present study is a prospective, randomised, control clinical study. A total of 70 individuals were included for the study; out of which 10 was dropped out to achieve a sample size of 60 patients which was randomly divided into two equal groups A and B. Group A is experimental group and group B is control group.

Duration and Design of the Study

This randomized clinical case control study was completed within 2 years of commencement.

Inclusion Criteria

Adult subjects of either sex between 30-60 years having elevated blood sugar level with subjective criteria of medadusti, meda vridhi and sthaulya or all and objective criteria as altered lipid profile were included in this study.

Exclusion Criteria

Subjects having PPBS > 300 mg/dL or having any other complication like- nephropathy, nephropathy, malignancy and pregnancy were excluded from this study.

Drug Information

Piper longum Linn. of Piperaceae family is an aromatic climber available in hotter parts of India and its fruit has been used in experimental group (group A) because of having katu-tikta rasa; laghu, snigdha, tikshna guna; anushna virya; Madhura vipaka and karma like-kapha-vatahara, Dipana, Hriday, rasayana and classically used in prameha.[7] Powder of pippali fruit has been administered at a dose of 3 gm/day in divided doses to group A.

Curcuma longa Linn. of Zingiberaceae, a perennial herb extensively cultivated in all parts of the country and its dried rhizome has been used in control group (group B). It has Katu, Tikta rasa; Ruksha guna; ushna virya; Katu vipaka and karma like kapha-pittaghna, pramehanasak.[8] Powder of Haridra dried rhizome has been administered at a dose of 3 gm/day in divided doses to group B.

Method and Schedule of Data Collection

The drugs were administered for 90 consecutive days for each patient for both the groups and objective parameters were assessed after 90 days from the date of registration. During this period, clinical parameters were assessed during follow ups after 30, 60 and 90 days.

Study Variables

Respective relevant objective parameters like- serum FBS, PPBS, HbA_1C, triglycerides (TG), total cholesterol and Lipoprotein A are the variables which were analysed statistically.

OBSERVATIONS AND RESULTS

Clinical Observations

Table 1: Distribution of Subjective criteria of Prameha of 60 patients of Prameha[9]

S. No.	Criteria	No. of Patient	Percentage (%)
1.	Kesajatilibhava (Matting of the hair)	15	25
2.	Asyamadhurya (Sweet taste in the mouth)	56	93
3.	Kara-pada Suptata (Numbness in the hands and feet)	50	93
4.	Kara-pada daha (Burning sensation in the hands and feet)	30	50
5.	Mukha-talu-kanthyasosha (Dryness in mouth, palate and throat)	45	75
6.	Pipasa (Thirst)	45	75
7.	Alasya (Laziness)	40	67
8.	Kayamala (Increased amount of excreta from the body)	20	33
9.	Kayacchidraupadeha (Adherence of excreta in the orifices of the body)	18	30
10.	Angaparidaha (Burning sensation in various organs of the body)	22	37
11.	Angasuptata (Numbness in various organs of the body)	28	47
12.	Satpadapipilikaabhisarana in sarira and mutra (Attraction of insects and ants by the body and urine)	19	32
13.	Mutradosha (Abnormalities in the urine)	25	42
14.	Vishrasariragandha (Smell of raw flesh in the body)	29	48
15.	Nidra (Excessive sleep)	29	48
16.	Tandra (Continuous drowsiness)	40	67
17.	Prabhutaavilamutrata (Excess turbidity of urine)	60	100

Table 2: Distribution of Subjective criteria of Oja Vibhramsa and Oja vyapat of 60 patients of Prameha[10]

S. No.	Criteria	No. of Patient	Percentage (%)
1.	Sandhi vishlesha (Looseness of the joints)	60	100
2.	Gatrasadan (Weakness of the body)	60	100
3.	Doshachyavan (Displacement of the doshas)	60	100
4.	Kriya sannirodha (Hindrance to all movements)	48	80
5.	Stabdhagatrata (Stiffness of the body)	48	80
6.	Guru Gaatrata (Heaviness of the body)	48	80
7.	Vatasopha (Oedema caused by Vata)	18	30
8.	Varna bheda (Discolouration)	33	55
9.	Glani (Exhaustion)	60	100
10.	Tandra (Stupor)	48	80
11.	Nidra (More of sleep)	36	60

Table 3: Follow up assessment of Subjective parameters of Prameha in 30 patients of group A

S. No.	Criteria	BT (%)	AT (%)	Curability rate (%)
1.	Kesajatilibhava (Matting of the hair)	25	15	40
2.	Asyamadhurya (Sweet taste in the mouth)	93	60	35.48
3.	Kara-pada Suptata (Numbness in the hands and feet)	93	35	62.37
4.	Kara-pada daha (Burning sensation in the hands and feet)	50	20	60
5.	Mukha-talu-kanthyasosha (Dryness in mouth, palate, and throat)	75	10	86.67
6.	Pipasa (Thirst)	75	25	66.67
7.	Alasya (Laziness)	67	30	55.22
8.	Kayamala (Increased amount of excreta from the body)	33	13	60.61
9.	Kayacchidraupadeha (Adherence of excreta in the orifices of the body)	30	20	33.33
10.	Angaparidaha (Burning sensation in various organs of the body)	37	16	56.76
11.	Angasuptata (Numbness in various organs of the body)	47	20	57.45
12.	Satpadapipilikaabhisarana in sarira and mutra (Attraction of insects and ants by the body and urine)	32	02	93.75
13.	Mutradosha (Abnormalities in the urine)	42	11	73.81
14.	Vishrasariragandha (Smell of raw flesh in the body)	48	8	83.33
15.	Nidra(Excessive sleep)	48	00	100
16.	Tandra (Continuous drowsiness)	67	09	86.57
17.	Prabhutaavilamutrata (Excess turbidity of urine)	100	26	74

Table 4: Follow up assessment of Subjective parameters of Oja Vibhramsa and Oja vyapat in 30 patients of group A

S. No.	Criteria	BT (%)	AT (%)	Curability rate (%)
1.	Sandhi vishlesha (Looseness of the joints)	100	28	72
2.	Gatrasadan (Weakness of the body)	100	39	61
3.	Doshachyavan (Displacement of the doshas)	100	65	35
4.	Kriya sannirodha (Hindrance to all movements)	80	25	68.75
5.	Stabdhagatrata (Stiffness of the body)	80	35	56.25
6.	Guru Gaatrata (Heaviness of the body)	80	20	75
7.	Vatasopha (Oedema caused by Vata)	30	15	50
8.	Varna bheda (Discolouration)	55	35	36.36
9.	Glani (Exhaustion)	100	55	45
10.	Tandra (Stupor)	80	26	67.5
11.	Nidra (More of sleep)	60	00	100

Table 5: Percentage of relief of subjective parameters of Prameha after treatment in group A

Percentage of relief	Remarks	Subjective parameter of Prameha and Oja Kshaya
100% improvement	Complete Remission	Parameter of Prameha: Nidra
		Parameter of Oja Kshaya: Nidra
≥ 75% to < 100% improvement	Marked improvement	Parameter of Prameha: Mukha-talu-kanthyasosha, Satpadapipilika abhisarana in sarira and mutra, Vishra sariragandha, Tandra
		Parameter of Oja Kshaya: Guru Gaatrata
≥ 50% to < 75% improvement	Moderate improvement	Parameter of Prameha: Kara-pada Suptata, Kara-pada daha, Pipasa, Alasya, Kayamala, Anga paridaha, Angasuptata, Mutradosha, Prabhuta avilamutrata
		Parameter of Oja Kshaya: Sandhi vishlesha, Gatrasadan, Kriya sannirodha, Stabdhagatrata, Vatasopha, Tandra.
≥ 25% to < 50% improvement	Mild improvement	Parameter of Prameha: Kesajatilibhava, Asyamadhurya, Kayacchidraupadeha,
		Parameter of Oja Kshaya: Doshachyavan, Varna bheda, Glani
< 25% improvement	No significant improvement	No such.

STATISTICAL OBSERVATIONS

Table 6: BT and AT results (Paired 't' Test) of objective parameters of Group A (N = 30)

S. No.	Objective Parameters	Mean		SD (±)	SE (±)	't' value	'p' value	Remarks
		BT	AT					
1	FBS	176.93	156.90	3.85	0.70	28.46	< 0.001	H.S.
2	PPBS	219.67	195.03	10.96	2.00	12.31	< 0.001	H.S.
3	HbA_1C	6.70	5.68	0.91	0.17	7.94	< 0.001	H.S.
4	Total Cholesterol	213.90	199.47	19.94	3.64	3.96	< 0.001	H.S.
5	Triglyceride	194.13	178.40	5.64	1.03	15.27	< 0.001	H.S.
6	Lipoprotein A	33.12	26.81	3.40	0.61	10.30	< 0.001	H.S.

Table 7: BT and AT results (Paired 't' Test) of objective parameters of Group B (N = 30)

S. No.	Objective Parameters	Mean		SD (±)	SE (±)	't' value	'p' value	Remarks
		BT	AT					
1	FBS	178.83	165.77	4.47	0.82	16.01	< 0.001	H.S.
2	PPBS	217.87	202.13	18.16	3.32	4.75	< 0.001	H.S.
3	HbA_1C	6.99	6.52	0.71	0.13	3.59	< 0.01	S.
4	Total Cholesterol	217.10	207.73	3.34	0.61	15.37	< 0.001	H.S.
5	Triglyceride	206.63	198.10	5.28	0.96	8.85	< 0.001	H.S.
6	Lipoprotein A	32.86	32.53	1.03	0.19	1.74	< 0.10	N.S.

Table 8: BT and AT results (Unpaired 't' Test) of Serum Lipoprotein A of patients of Prameha (N = 60)

Parameter	SD (±)	SE (±)	t value	P value	Remarks
Lipoprotein A	2.50	0.65	9.17	<0.001	Highly Significant

Table 9: ANOVA of Serum Lipoprotein A of patients of Prameha (N = 60)

Square of variance	df	sum of square	mean sum of square	F-ratio
Between the classes	1	540.61	540.61	30.86
Error	58	1016.13	17.52	
Total	59	1556.74		

H.S. - Highly significant (P < 0.001), S. - Significant (P < 0.05), N.S. - Non-significant (P > 0.05)

DISCUSSION

It has been found that the disease prameha including madhumeha is a kapha predominant tridoshaja vyadhi[11]. Vata and pitta accelerates kapha in such a way that it becomes Bahudrava i.e. the guna of kapha gets produced[12]. Hence kapha loses its structural, functional and physiological aspect; hence it becomes unable to provide nourishment to all the Sthayi and Asthayi dhatus. As meda and kapha are identical in nature by the virtue of its panchabhoutika guna, it affects particularly meda dhatu at a great extent[13]. As a result, extensive medadusti occurs in prameha. Medouja is the ultimate essence of meda dhatu yield as a derivative of dhatu paka. Along with medadusti, medouja dushti also takes place[14] in terms of aparoja dushti. On relationship of medouja with Lipoprotein, it is found that alteration of lipid profile is caused by depletion of lipoprotein. Hence in diabetes mellitus, structural and functional destruction of lipoprotein occur. It affects lipid peroxidation at cellular level. This phenomenon also affects lipid metabolism within circulation. As a result, the lipid profile of an individual gets altered. So, alteration of lipoprotein at basic level affects lipid metabolism at systemic level. Hence, it supports the pathophysiology of hypoglycaemia in diabetes would be termed as meda and medouja-dushti in prameha.

On the other hand, it is proven that lipoprotein A alters in prameha and as a result features of Oja Vibhramsa and Oja Vyapat are reflected in patients. Statistically comparing between two groups, the result has been obtained that the 't' value (28.46, 12.31, 7.94, 3.96, 15.27 and 10.30 respectively) of FBS, PPBS, HbA_1C, Total Cholesterol, Triglyceride and Lipoprotein A as the objective criteria in the experimental group is much more higher than the control group ('t' value- 16.01, 4.75, 3.59,15.37, 8.85 and 1.74 respectively). Result of Lipoprotein A in Paired't' test shows p value < 0.001 in experiment group (significant) and < 0.10 in control group (non-significant). The percentile curability rate of subjective criteria of prameha and oja Vikriti in the experimental group is also significant. Pippali showed its efficacy in these patients more significantly than Haridra. Follow up assessment shows highly significant clinical improvement in these patients. But statistically it is established Group A had showed highly significant results (p < 0.001) in all the objective parameters where group B had showed result as highly significant (p < 0.001) in FBS, PPBS, Total Cholesterol and TG, significant (p < 0.1) in HbA_1C and non-significant in Lipoprotein A. Even Unpaired 't' test proved the study as highly significant (p < 0.001) as a whole for the better result in group A. The calculated 'F' ratio is compared at a df between the groups and df within the groups at 5% level. The 'F' value at df = 1 across **(→)** and df=58 vertically **(↓)** at 5% level, is significant. The computed 'F' ratio is greater than table 'F' ratio (critical ratio). Hence, the alleviation rate of Lipoprotein A between the two groups differs significantly and the experiment group shows the higher curability rate than the control group.

CONCLUSION

Medadusti is an essential phenomenon in the pathogenesis of prameha. Medouja is a fundamental element which protects the meda and gets depleted in this disease prameha. This very statement has been propounded by Acharya Charaka and it is supported by the theory of hyperlipidaemia in hyperglycaemia. In the present study, the effect of pippali (*Piper longum* Linn.) has been observed for a period of 90 days in patients of prameha

existing with hyperlipidaemia. An interventional, prospective, randomised, control trial has been carried out on 60 patients with 30 patients in each group. The obtained data shows marked to moderate improvement of subjective criteria of prameha and oja Vikriti as an effect of pippali. In Paired 't' test in experiment group, pippali is showing the excellent result in combating hyperlipidaemia, hyperglycaemia and alleviating Lipoprotein A. Unpaired 't' test between experiment and control group reveals that certainly pippali is exerting better result than Haridra ('t' value- 9.17, 'p' value- < 0.00). Hence, it can be concluded that pippali is an excellent remedy to combat medouja dushti through preventing the destruction of medouja and curing prameha. Probable mode of action of pippali can be described as below

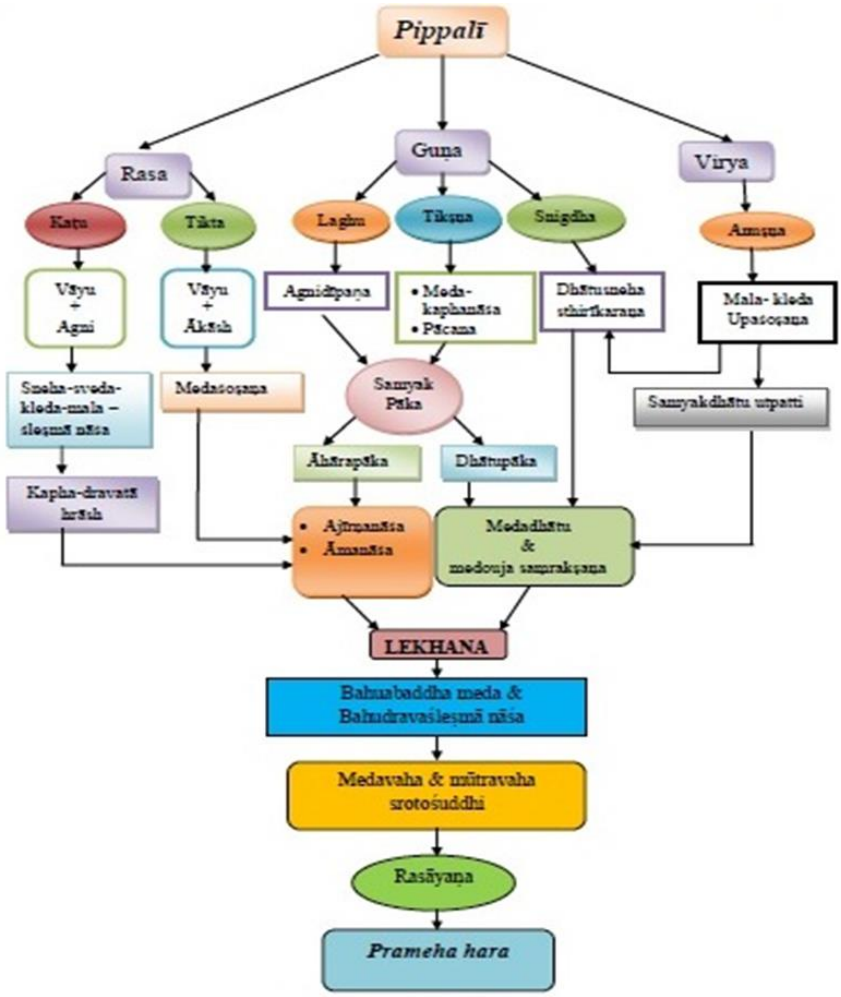

Figure 1: Probable mode of action of pippali

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