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Research Article

CLINICAL EVALUATION OF MEDADUSTI IN PRAMEHA WITH SPECIAL REFERENCE TO HYPERLIPIDEMIA IN TYPE II DIABETES MELLITUS

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ABSTRACT

Classically it has been mentioned that Bahudrava Kapha and Bahuabad dhameda are the causative factors in the disease Prameha. Clinically Prameha can be correlated with type II Diabetes mellitus. Sequels of hyperlipidemia are found in the course of disease of Diabetes mellitus. Hence in this study the efficacy of Pippali was evaluated to reduce non-beneficial saturated circulatory lipids and as well as to control Diabetes mellitus. This study was a prospective, randomised and control clinical study with two groups, having 20 patients each, of which one was treated with Pippali and another with Haridra respectively considered as group A and group B (control). Patients were selected from OPD and IPD of the institute - Institute of Post Graduate Ayurvedic Education and Research at Shyamadas Vaidya Shastra Peeth Hospital irrespective of sex and religion. Selection was done as per subjective criteria of Prameha and Medadusti and objective criteria of FBS, PPBS and Lipid profile. Exclusion and inclusion criteria also followed. Pippali had been administered orally at a dose of 3 gm/day at divided doses. Before treatment and after treatment effects had been assessed statistically. Before treatment and after treatment assessment of blood sugar and lipid profile estimation had shown a significant reduced value of blood sugar and blood lipid level with a P-value of < 0.001. Virtually having katu rasa and ushnavirya, Deepana and pachana activities of Pippali pacify the aggravation of kapha. Its laghu and ruksha properties help to reduce the lipids. This combined effect controls hyperlipidemia and hyperglycemia in Diabetes mellitus.

Keywords: *Bahudrava Kapha, Bahuabaddhameda, Prameha,* type II Diabetes mellitus, *Pippali,* hyperlipidemia.

INTRODUCTION

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 hyperlipidemia. 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 hyperlipidemia plays a major role in these complications. Causes of hyperlipidemia 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 Bahudravakapha and Bahuabaddhameda are the main causative factors in pathogenesis of prameha[2]. Hence, medadusti is a very essential factor in pathogenesis of Prameha. Present study aimed to evaluate the reduction of non-beneficial saturated circulatory lipids along with reduction of blood glucose level by the administration of Pippali (*Piper longum* Linn.).

MATERIAL AND METHODS

Brief account of present knowledge

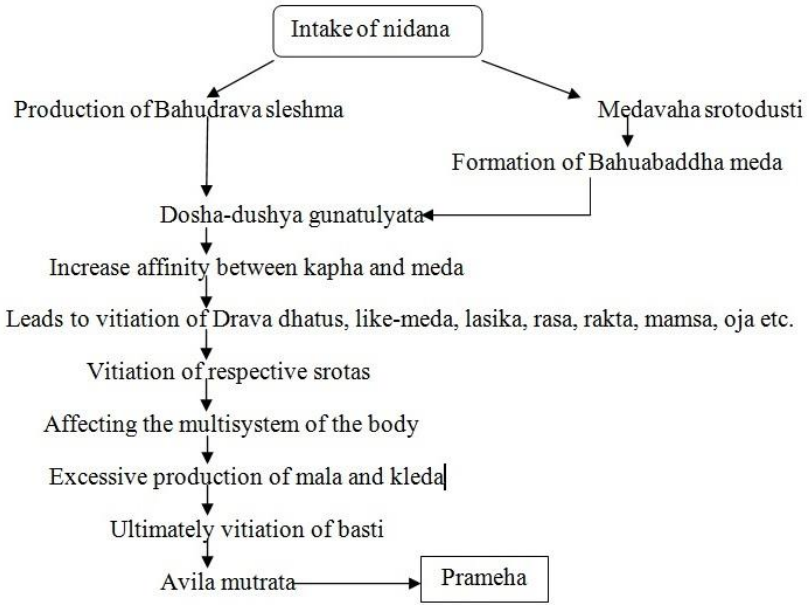
Diabetes mellitus, being a multisystem affecting disease, produces disability. Recently, its global prevalence is a burning problem socially and economically. This disease is identified by elevated blood sugar level.

FBS--- < 100 mg/dL– Normal
100-125 mg/dL- Impaired glucose tolerance
> 126 mg/dL—Diabetes

PPBS--- < 140 mg/dL - Normal
140- 199 mg/dL - Impaired glucose tolerance
>199 mg/dL – Diabetes.[3]

It has been reported that hyperlipidemia is a common presentation in Diabetes mellitus. Also, the obese persons have the risk factor to achieve Diabetes mellitus. Primarily triglycerides remain at a higher level than the other lipoproteins. Due to insulin insensitivity the cells suffer in a hypoglycaemic state just due to low glucose environment which triggers breakdown of adipose tissues into triglycerides. Elevated TG in blood increases LDL levels in the circulation. In this condition, if the dietary habit (fatty foods) and lifestyle of an individual are unwholesome that much it can be favourable to create this disease, cholesterol level may be increased in blood. This phenomenon has been supported

classically as medadusti which is denoted as a causative factor in pathogenesis of Prameha.[4] Classically, Diabetes mellitus is correlated with Prameha and here, the conversion of serum to extreme sweetness which can be detected by anumana.[5] The main causative factor of prameha is Bahuabaddhameda and Bahudravasleshma. The pathogenesis of the disease in schematic diagram had been showed in the following-



Selection of Subjects

Patients were selected as known diabetic from OPD of the institute- Institute of Post Graduate Ayurvedic Education and Research at Shyamadas Vaidya Shastra Peeth Hospital according to the blood glucose level, FBS and PPBS not exceeding 200 mg/dL and 300 mg/dL respectively. The subjective criteria of medadusti, medavriddhi and sthoulya are verified on those patients and the objective criteria of lipid profile (specifically triglyceride, total cholesterol, and LDL) have been assessed on them to search out medadusti. 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). Subjective and objective criteria had been analysed clinically and statistically to evaluate the efficacy of Pippali both in Prameha and medadusti.

Sample Size and Sample Design

A total of 49 individuals were included for the study; out of which 9 was dropped out to achieve a sample size of 40 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 18 months of commencement.

Inclusion criteria

Adult subjects of either sex between 30-60 yrs having elevated blood sugar level with subjective criteria of medadusti, medavriddhi and sthoulya 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 in 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 (pungent) predominant madhura and tikta rasa (sweet and bitter taste); laghu (light), snigdha (unctuous), tiksnaguna (sharpness); anushnavirya (medium potency); madhuravipaka and karma like-kapha-vatahara (pacifies kapha and vata), dipana (digestion and metabolism enhancing), Hridya (beneficial for heart), rasayana (rejuvenation) and classically used in prameha.[6] 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 (pungent-bitter taste); Rukshaguna (dry property); ushnavirya (hot in potency); Katuvipaka and karma like kapha-pittaghna (pacifies kapha and pitta), pramehanasak.[7] 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, triglycerides (TG), total cholesterol and low-density lipoprotein (LDL) are the variables which were analysed statistically.

RESULT

Table 1: Clinical Assessment of Subjective Criteria (group A) [8-10]

	Subjective Criteria	BT	After 30 days	After 60 days	After 90 days	AT
1.	Medadustilakshana-----					
a.	Jatilibhavkesha (Matting of the hair)	++	++	++	+	+
b.	Asyamadhurya (Sweet taste in the mouth)	+++	++	++	+	+
c.	Karapadasuptata (Numbness in the hands and feet)	+	+	+	-	-
d.	Karapadadaha (Burning sensation in the hands and feet)	++	++	+	-	-
e.	Mukha-talu-kantha sosha (Dryness in mouth, palate and throat)	-	-	-	-	-
f.	Pipasa (Thirst)	-	-	-	-	-
g.	Alasya (Laziness)	++	++	++	+	+
h.	Kayamala (Increased amount of excreta from the body)	-	-	-	-	-
i.	Kayacchidraupadeha (Adherence of excreta in the orifices of the body)	++	++	+	-	-
j.	Paridaha (Burning sensation in various organs of the body)	+	+	-	-	-
k.	Angasuptata (Numbness in various organs of the body)	++	++	-	-	-
l.	Satpadpipilikasariramutrabhisarana (Attraction of insects and ants by the body and urine)	+	-	-	-	-
m.	Mutradosha (Abnormalities in the urine)	+++	+++	++	+	+
n.	Vishrasariragandha (Smell of raw flesh in the body)	++	++	+	-	-
o.	Nidra (Excessive sleep)	+	+	-	-	-
p.	Tandra (Continuous drowsiness)	+	-	-	-	-
2.	Medavriddhilakshana---					
a.	Snigdhangata (unctuousness of the body)	+	+	+	+	+
b.	Udara-parshavriddhi (increased size of abdomen and flanks)	+	+	+	-	-
c.	Kasa (cough)	++	+	+	+	+
d.	Swasa (breathlessness)	+	+	-	-	-
e.	Daurgandha (bad smell from the body)	++	++	+	-	-
3.	Sthaulyalakshana---					
a.	Chalasphig-udara-stana (movement of buttock, abdomen and breasts)	+	+	+	-	-
b.	Ayathaupachaya-utsaha (fatigability)	+	+	+	+	+
c.	Atisthula (excessive fatty)	+	+	+	+	+

Symptomatic Relief = 75.76%

Table 2: Clinical Assessment of Subjective Criteria (group B) [11-13]

	Subjective Criteria	BT	After 30 days	After 60 days	After 90 days	AT
4.	Medadustilakshana-----					
a.	Jatilibhav kasha (Matting of the hair)	++	++	++	+	+
b.	Asyamadhurya (Sweet taste in the mouth)	+++	+++	++	++	++
c.	Karapadasuptata (Numbness in the hands and feet)	++	++	+	-	-
d.	Karapadadaha (Burning sensation in the hands and feet)	++	+	-	-	-
e.	Mukha-talu-kantha sosha (Dryness in mouth, palate and throat)	-	-	-	-	-
f.	Pipasa (thirst)	+	+	+	-	-
g.	Alasya (laziness)	++	++	+	+	+
h.	Kayamala (Increased amount of excreta from the body)	-	-	-	-	-
i.	Kayacchidraupadeha (Adherence of excreta in the orifices of the body)	++	+	+	+	+
j.	Paridaha (Burning sensation in various organs of the body)	+	+	+	-	-
k.	Angasuptata (Numbness in various organs of the body)	++	++	+	+	+
l.	Satpadpipilikasariramutrabhisarana (Attraction of insects and ants by the body and urine)	+	+	+	+	+
m.	Mutradosha (Abnormalities in the urine)	+++	+++	++	++	++
n.	Vishrasariragandha (Smell of raw flesh in the body)	++	++	++	+	+
o.	Nidra (Excessive sleep)	+	+	+	-	-
p.	Tandra (Continuous drowsiness)	+	+	+	+	+
5.	Medavriddhilakshana---					
a.	Snigdhangata (unctuousness of the body)	-	-	-	-	-

b.	Udara-parshavriddhi (increased size of abdomen and flanks)	+	+	+	+	+
c.	Kasa (cough)	++	++	++	++	++
d.	Swasa (Breathlessness)	++	++	+	+	+
e.	Daurgandha (bad smell from the body)	++	++	++	+	+
6.	Sthaulyalakshana---					
a.	Chalasphig-udara-stana (movement of buttock, abdomen and breasts)	+	+	+	-	-
b.	Ayathaupachaya-utsaha (fatigability)	++	++	++	++	++
c.	Atisthula (excessive fatty)	++	++	++	+	+

Symptomatic Relief = 48.65%

Table 3: Analysis of objective Criteria of Prameha (group A)

Objective parameter of Prameha	Mean	SD (±)	SE (±)	't' value	P	Remarks
FBS	16.05	4.83	1.08	14.86	< 0.001	Significant
PPBS	16.85	3.87	0.87	19.37	< 0.001	Significant

Table 4: Analysis of objective Criteria of Medadusti (group A)

Objective parameter of Medadusti	Mean	SD (±)	SE (±)	't' value	P	Remarks
TG	12.55	9.98	2.23	5.62	< 0.001	Significant
Total Cholesterol	14.25	7.99	1.79	7.96	< 0.001	Significant
LDL	14.10	7.24	1.62	8.70	< 0.001	Significant

Table 5: Analysis of objective Criteria of Prameha (group B)

Objective parameter of Prameha	Mean	SD (±)	SE (±)	't' value	P	Remarks
FBS	9.65	3.66	0.82	11.77	< 0.001	Significant
PPBS	8.35	2.66	0.59	14.15	< 0.001	Significant

Table 6: Analysis of objective Criteria (group B)

Objective parameter of Medadusti	Mean	SD (±)	SE (±)	't' value	P	Remarks
TG	7.25	3.85	0.86	8.43	< 0.001	Significant
Total Cholesterol	5.65	3.92	0.88	6.4	< 0.001	Significant
LDL	5.15	3.56	0.80	6.44	< 0.001	Significant

DISCUSSION

The obtained data shows that both the drugs of experimental and control group are effective as p < 0.001. But the clinical assessment of subjective criteria had been shows that achieved improvement is better in the experimental group which has been supported by the statistical data analysis of variance. In the experimental group, mean of FBS, PPBS, TG, Total Cholesterol and LDL are 16.5, 16.85, 12.55, 14.25 and 14.1 respectively; where in group B, the values are 9.65, 8.35, 7.25, 5.65 and 5.15. In the experimental group, SD **(±)** of FBS, PPBS, TG, Total Cholesterol and LDL are 4.83, 3.87, 9.98, 7.99 and 7.24; respectively; where in group B, the values are 3.66, 2.66, 3.85, 3.92 and 3.56. The values of SE **(±)** revealed in experimental group are 1.08, 0.87, 2.23, 1.79 and 1.62 respectively and in control group shows 0.82, 0.59, 0.86, 0.88 and 0.80 respectively. In statistical analysis, the degree of freedom (df = 19) shows t values and from which p value revealed < 0.001 (highly significant) in both the groups. But depending upon subjective and objective criteria, group A is more significant than group B. So, it can be clearly declared that Pippali is more potent than Haridra in cases of hyperlipidemia in Prameha. Probable mode of action of Pippali can be described as below-

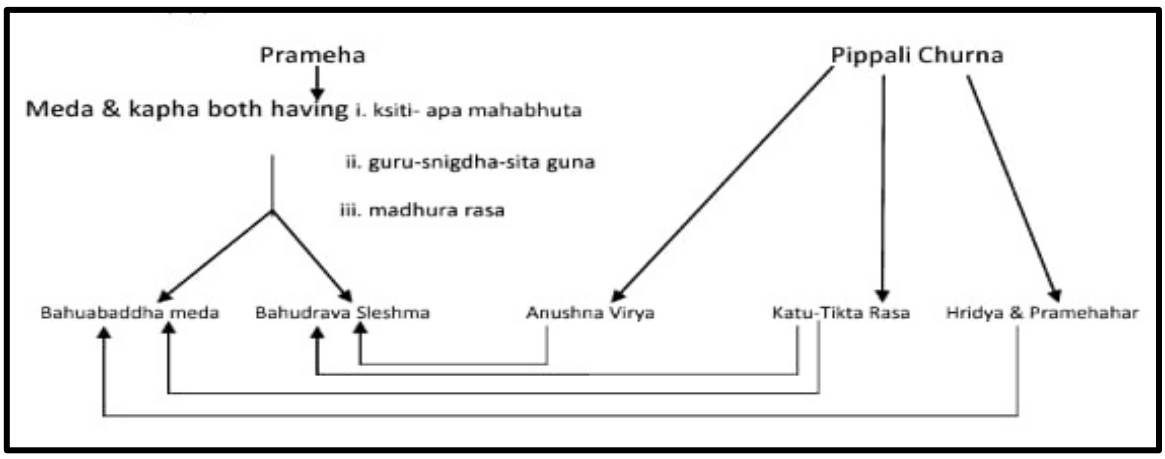


Figure 1: Probable mode of action of Pippali

CONCLUSION

Medaduṣṭi is an essential phenomenon in the pathogenesis of prameha. Pippali and haridra both act as medahara and pramehaghna. But observing the subjective and objective criteria, it is very much clear that Pippali is comparatively better than haridra to combat medadusti as well as prameha. It has been clearly depicted that medavahasrotodusti is the causative factor of prameha and it can be successfully treated by Pippalichurna being capable to combat Bahuabaddhameda and Bahudrava Sleshma.

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