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A Critical study of *Pramehahara* effect of *Dhaatri Nishe* w.s.r. to Diabetes mellitus

Research Article

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Abstract

Nishaamlaki is a known Ayurvedic medicinal preparation which is found effective in controlling the Diabetes mellitus. But according to *Astanga hridaya* "*Meheshudhaatrinishe*" combination of *Aamlaki* and two *Haridra* drugs effectively controls *Prameha*.Here the word "*NISHE*" indicates two drugs i.e., *Haridra* and *Daruharidra.*The combination of *Aamlaki* (*Emblica officinalis* Linn.*) Haridra* (*Curcuma longa* Linn.) and *Daruharidra* (*Berberis aristata* D.C *& Coscinium fenestratum* Colebr.) is to be considered as "*Srestha*" (Drug of choice) in Diabetes mellitus. India leads the world's largest number of diabetic subjects earning the dubious distinction of being termed the diabetes capital of the world. According to diabetes atlas 2008 published by Indian diabetic federation, the number of people with diabetes in India are currently around 40.9 million and is expected to rise to 69.9 million by 2025 unless urgent preventive measures are taken. In India, it is also 3rd leading cause of death (After heart disease and cancer).It has turned out to be the biggest "silent killer" in today's world. The present research work is done on 60 patients dividing them into 2 groups.DH1 Group was given with *Aamalaki, Haridra and Daruharidra* {*Berberis aristata* D.C}, DH2 Group was given with *Aamalaki, Haridra and Daruharidra* {*Coscinium fenestratum* Colebr.}. Finally it is concluded that *Daruharidra* which is known botanically as *Berberis aristata* D.C is highly effective in controlling the blood sugar levels in combination with *Aamalaki* and *Haridra* than *Coscinium fenestratum* Colebr. in combinations with *Aamalaki* and *Haridra.*

Keywords: *Prameha,* Diabetes Mellitus, *Dhaatrinishe*, *Daruharidra*.

Introduction

Diabetes mellitus is one of the most common metabolic disorders. According to WHO "Diabetes is a major threat to global public Health that is rapidly getting worse, and the biggest impact is on adults of working age in developing countries" The total number of recorded diabetes patients till the year 2000 are 171 million and expecting to be increased by 366 million by the year 2030 (1). *Prameha* may be compared to diabetes mellitus because of the similarities in etiology, pathogenesis, clinical features & prognosis. Main Aim of *Ayurveda* is to cure the disease & maintain health state, *Ayurveda*-the science of life-though has its own principles, is incorporating new theories and drugs in it and presenting them according to its principles. *Nishaamlaki* is already known in Ayurvedic field and found effective in certain cases of Diabetes mellitus,But according to *Asthanga hridaya* while describing *Agryasangraha Meheshudhaatrinishe* is said to be best for Diabetes mellitus(2).

Few scholars have contributed their best on this topic and proved *Haridra* and *Aamalaki*'s role in *Prameha*. The present study is designed to add one more step to those contributions adding of *Daruharidra* and *Haridra* along with *Aamalaki.* According to Acharya Indu while commentating on'*Nishe*', in *Astangasamgraha* he mentioned *Nishe* as *Pindaharidra* and *Daruharidra* (3). *Pindaharidra* is a synonym of *Haridra*. Hence *Nishe* means *Haridradwaya*. Considering this *sutra,* we further move forwarded and prepared *Dhaatrinishe* compound preparation with the combination of *Haridradwaya* and *Aamalaki* as per Indu.

Regarding the identity of *Daruharidra*, two plant spices are extensively used in the northern and southern parts of India. They are *Berberis aristata* D.C. and *Coscinium fenestratum* colebr. The present study is aimed to exactly identify the best combination in controlling Diabetes mellitus adding two varieties of *Daruharidra* to *Haridra* and *Aamalaki* in different combinations.

Aims and objectives

To study the *Srestatha* of *Aamlaki*, *Haridra* & *Daruharidra* Combination to control prameha with reference to Diabetes mellitus as envisaged by *Vagbhata -II*

To compare the effectiveness of *Daruharidra* (*Coscinium fenestratum* colebr. *& Berberis aristata* D.C.*)* in combinations with *Aamalak*i & *Haridra.*

To evolve an effective drug having *Pramehahara* action as per the classical literature of Ayurveda.

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Clinical Study

Materials and Methods

The patients having classical symptoms of Diabetes Mellitus have been selected from OPD of PG Department Of *Dravyaguna*, *S.V. Ayurvedic Hospital,* TTD, *Tirupati,* irrespective of Sex, Religion, and Occupation etc.

A special detailed Clinical Pro forma has been prepared incorporating selected symptoms and signs based on both *Ayurvedic* and Modern description of the disease.

A detailed history has been taken and complete physical examination has been carried out.

Plan of Study

Inclusion Criteria

- Age group between 30-70 years.
- Fulfilment of Diagnostic Criteria.

Diagnostic Criteria

Signs and symptoms of DiabetesMellitus

Prabhutamutrata (Polyuria), *Pipasaadhikayta* (Polydipsia), *Kshuda adhikya* (Polyphagia), *Kara pada daha* (Burning sensation in feet & hands), *Swedaadhikyata* (Perspiration), *Daurbalya* (Weakness) and *Pindikodwestana* (Cramps).

Standard criteria of National Diabetes Data group and W.H.O. for DM was adopted which are as follows: (Adopted by American Diabetic Association).

- Fasting blood glucose ≥126 mg/dl (or)
- Postprandial blood glucose ≥200 mg/dl

Exclusion Criteria

- Patients suffering from any severe Systemic disease.
- Patients who are above below 30 years of Age and 60 Years of Age
- Type 1 DM inclusive dependent types of other DM cases
- Patients suffering from the complications of DM

Method of Study/ Study Design:

- Number of Groups
  1. DH1 Group (*Aamalaki, Haridra and Daruharidra* {*Berberis aristata* D.C})
  2. DH2 Group (*Aamalaki, Haridra and Daruharidra* {*Coscinium fenestratum* Colebr.})
- Dose - 500 mg 2 capsules B.D for 60 days
- Dosage form - Capsule
- Administration -Before meals
- Duration - 60 Days
- Vehicle – Water

Diet & Regimen

Patients were asked to go for Aerobic exercises for 15-20 minutes in a day along with other routine physical works as a part of their regular activities. They were advised to avoid *Kaphavardhaka Ahara*, day sleep, alcohol, high calorie diet etc.

Follow-up

All the patients were reviewed for their fasting blood sugars and postprandial blood sugars on 30th day and 60thday during the treatment.

Investigations:

- Fasting blood sugar levels (FBS)
- Postprandial blood sugar levels (PPBS)

Criteria for the Assessment

- Alleviation in the signs and symptoms of the disease as per *Ayurvedic* texts.
- Biochemical Investigations before and after the treatment.

Subjective criteria

The changes observed in the signs and symptoms were assessed by adopting suitable scoring pattern and the objective signs by using appropriate clinical tools. The detail assessment of clinical signs and symptoms are as follows:

1. Polyuria (*Prabhuta Mutrata)*	**Grading**
3 – 5 times per day, no or rarely at night	0
6 – 8 times per day, 1 – 2 times per night	1
9 – 11 times per day, 3 – 4 times per night	2
> 11 times per day, > 4 times per night	3
2) Polydipsia *(Pipasa – Adhikya)*	
Absent (Taking 8-10 glass of water daily)	0
Patient is taking 10-15 glass/day & getting satisfaction	1
Patient is taking 15- 20 glass/day & not getting satisfaction	2
Patient is taking 20-25 glass/day & not getting satisfaction	3
3) Polyphagia (*Kshudha- Adhikya)*	
As usual / routine	0
Slightly increased (4 – 5times)/day	1
Moderately increased (6 –7times)/ day	2
Markedly increased (8 – 9times)/day	3
4) Burning sensation in feet & hands *(Kara-Pada daha)*	
No *Pada daha*	0
Kara-Pada daha not continuous	1
Kara-Pada daha continuous but bearable & not severe	2
Kara-Pada daha continuous, severe & Unbearable	3
5) Perspiration (*Swedadhikya)*	
Sweating after some strenuous or heavy work or in hot & humid weather	0
Profuse sweating after moderate work and movement	1
Sweating after little extra work than routine and movement	2
Profuse sweating after routine work	3

6) Weakness (*Daurbalya)*

Can do routine exercise/work	0
Can do moderate exercise with hesitancy	1
Can do mild exercise only, with difficulty	2
Cannot do mild exercise too	3

7) Cramps (*Pindikodveshtana)*

No cramps	0
Cramps after walking more than 1 km	1
Cramps after walking ½ km	2
Inability in walking even ½ km	3

Objective criteria

Bio-chemical investigations like Fasting blood sugars (FBS), postprandial blood sugars (PPBS) were performed before and after treatment.

Fasting blood glucose ≥126 mg/dl or Postprandial blood sugar levels ≥200 mg/dl

Assessment of overall effect of Therapy :

The result obtained from individual patient was categorized according to the following grades:

Statistical analysis:

The gathered information was subjected to statistical analysis in terms of Mean, Standard Deviation and Standard Error. Paired "t" test was carried out at $p<0.05$, $p<0.01$, $p<0.001$. The obtained results were interpreted as:

- Insignificant : $p\geq0.05$
- Significant : $p\leq0.05$
- Very significant : $p\leq0.001$
- Extremely significant : $p\leq0.0001$

DH1 GROUP:

This group consists of combination of *Aamalaki, Haridra, Daruharidra* (*Berberis aristata* D.C.)

500 mg 2 Capsules with Water twice in a day half an hour before food for 60 days

Table 1. Showing subjective parameter results of DH1Group patients

Parameter	Mean		SD		SEM		df	t value	p value	Significance
	B.T	A.T	B.T	A.T	B.T	A.T				
Polyuria	2.45	0.70	0.51	0.73	0.11	0.16	19	17.616	≤0.0001	Extremely significant
Polydipsia	1.85	0.90	0.72	0.51	0.08	0.16	19	5.5964	≤0.0001	Extremely significant
Polyphagia	1.20	0.55	0.41	0.69	0.09	0.15	19	4.9509	≤0.0001	Extremely significant
Burning sensation in feet & hands	1.25	0.60	0.44	0.68	0.10	0.15	19	4.9509	≤0.0001	Extremely significant
Perspiration	1.20	0.45	0.41	0.69	0.09	0.15	19	6.0970	≤0.0001	Extremely significant
Weakness	1.45	0.55	0.51	0.69	0.11	0.15	19	6.2818	≤0.0001	Extremely significant
Cramps	1.20	0.65	0.41	0.75	0.09	0.17	19	4.8189	≤0.0001	Extremely significant

DH2 group statistical data:

This group consists of combination of *Aamalaki, Haridra, Daruharidra* (*Coscinium fenestratum* Colebr.)

500 mg 2 Capsules with Water twice in a day half an hour before food for 60 days

Table 2.Showing subjective parameter results of DH2 Group patients

	Mean		SD		SEM		df	t value	p value	Significance
	B.T	A.T	B.T	A.T	B.T	A.T				
Polyuria	1.65	1.10	0.75	0.55	0.17	0.12	19	2.7729	0.0121	Significant
Polydipsia	1.30	0.70	0.47	0.57	0.11	0.13	19	3.9428	0.009	Extremely significant
Polyphagia	1.25	0.65	0.44	0.49	0.10	0.11	19	4.4853	0.0003	Extremely significant
Burning sensation in feet & hands	1.25	0.65	0.44	0.59	0.10	0.13	19	3.9428	0.009	Extremely significant
Perspiration	1.10	0.75	0.45	0.44	0.10	0.10	19	3.1986	0.0047	Very Significant
Weakness	1.40	1.10	0.60	0.64	0.13	0.14	19	2.48536	0.0102	Significant
Cramps	1.05	0.65	0.76	0.59	0.17	0.13	19	3.5590	0.0021	Very Significant

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Table 3.Showing results of DH1 Group Blood sugar levels

	Mean		SD		SEM		df	t value	p value	Significance
	B.T	A.T	B.T	A.T	B.T	A.T				
FBS	195.65	146.10	63.36	45.24	14.17	10.12	19	7.8545	≤0.0001	Extremely Significant
PPBS	223.35	174.95	57.17	35.82	12.78	8.01	19	6.6414	≤0.0001	Extremely Significant

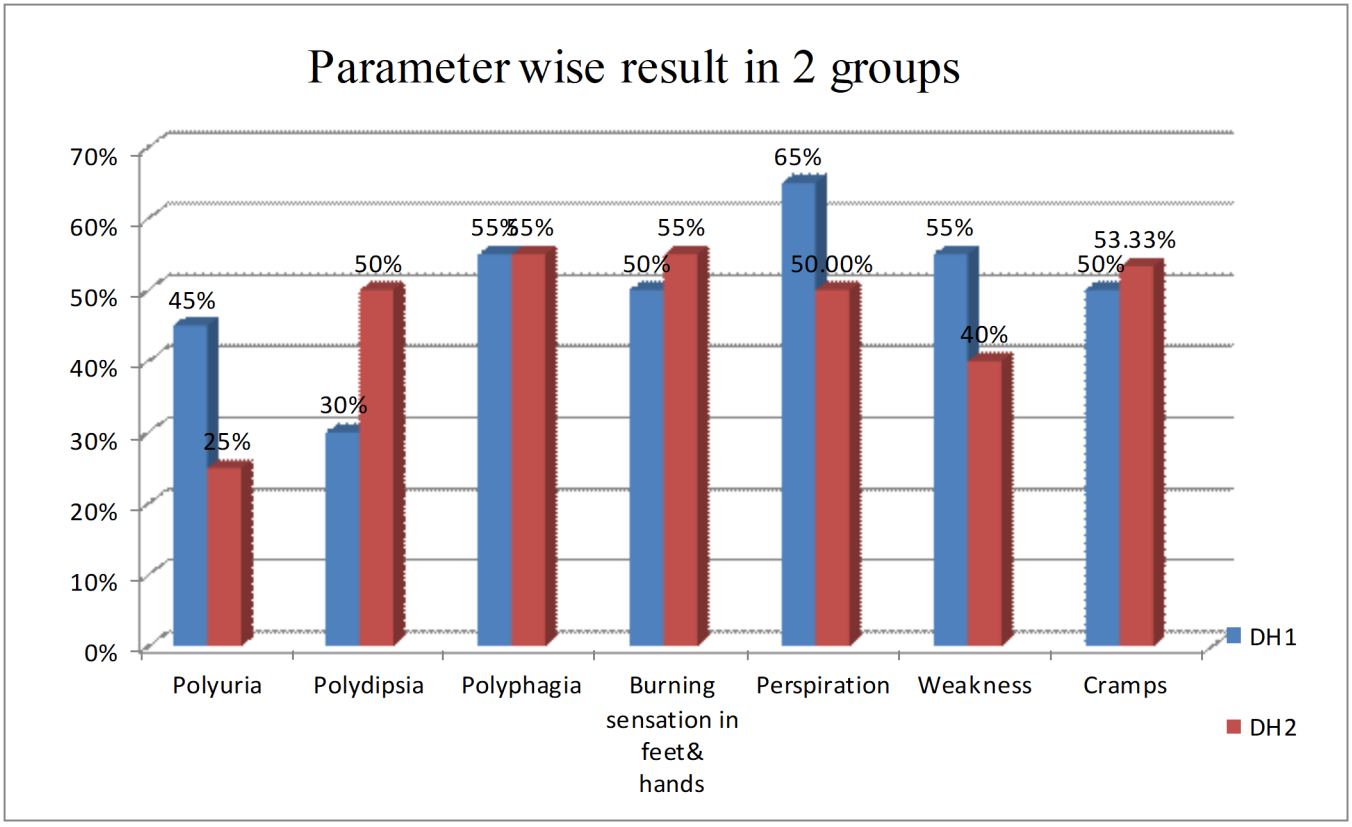
Table 4.Showing results of DH2 Group Blood sugar levels

	Mean		SD		SEM		df	t value	p value	Significance
	B.T	A.T	B.T	A.T	B.T	A.T				
FBS	178.10	168.15	33.25	28.28	7.43	6.32	19	3.1482	0.0053	Very significant
PPBS	219.05	204.05	53.46	45.84	11.95	10.25	19	3.0995	0.0059	Significant

Table 5.Showing Subjective Parameter wise result in 2 groups

Parameter	DH1	DH2
Polyurea	45%	25%
Polydipsia	30%	50%
polyphagia	55%	55%
Burning sensation in feet and Hands	50%	55%
Perspiration	65%	50%
Weakness	55%	40%
Cramps	50%	53.33%

Graph No.1.Showing Parameter wise result in 2 groups



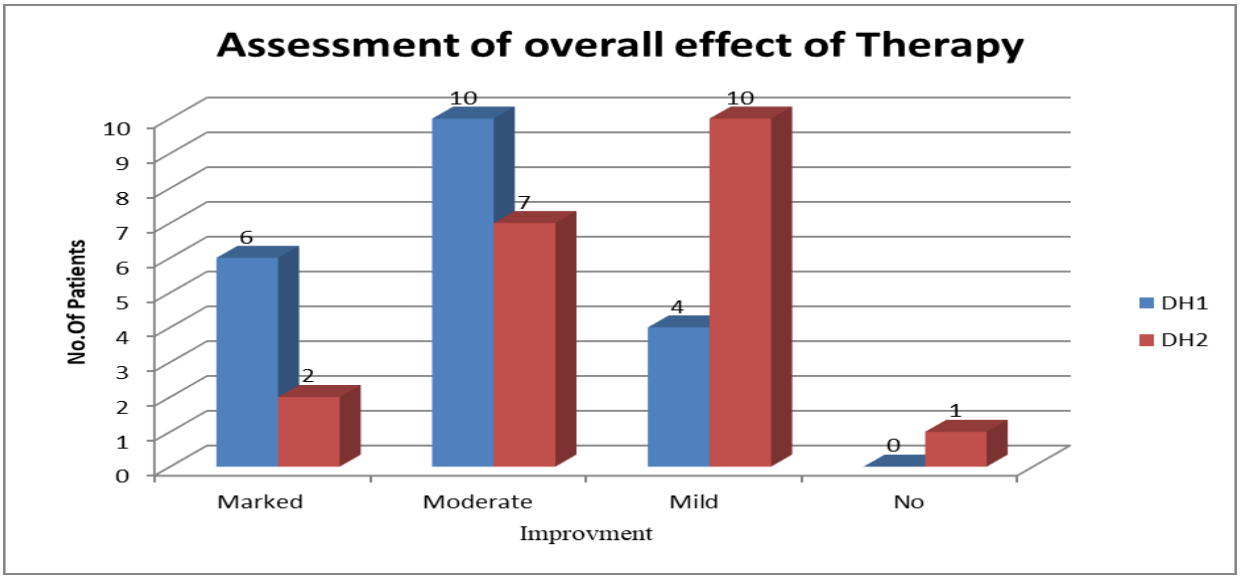
Assessment of overall effect of Therapy

The result obtained from individual patient was categorized according to the following grades:

Table 6.Assessment of overall effect of Therapy

	Improvement	Percentage of relief	DH1	DH2
1	Marked improvement	≥ 75% to 100% relief	6	2
2	Moderate improvement	≥ 50% up to74.99% relief	10	7
3	Mild improvement	≥ 25% up to 49.99% relief	4	10
4	No improvement	< 25% relief	0	1

Graph 2.Assessment of overall effect of Therapy



Discussion

The treatment continued for a period of 60 days for all the members of both of the groups and blood sugar levels are assessed at periodic intervals before and after treatment. At the end of 60 days the total results of the entire work was tabulated and were subjected for statistical study to clearly demonstrate the effect of 2 groups on the course of disease along with the values of significance.

At the end of 60 days fasting blood sugar levels of DH1 group patients have come down significantly, in comparison with the levels before the commencement of treatment. The t-test implied as 7.85 which is extremely significant at 0.01 levels. Postprandial blood sugar levels have come down significantly, in comparison with the levels before the commencement of treatment. The t-test implied as 6.64 which is extremely significant at 0.01 levels in the same group.

At the end of 60 days fasting blood sugar levels of DH2 group have come down significantly, in comparison with the levels before the commencement of treatment. The t-test implied as 3.14 which is very significant at 0.05 levels. Postprandial blood sugar levels have come down significantly, in comparison with the levels before the commencement of treatment. The t-test implied as 3.09 which is significant at 0.05 levels in the same group.

In the DH1 group 6 patients were showed marked improvement, 10 patients showed moderate improvement and 4 patients showed mild improvement in the total number of 20 patients.

In the DH2 group 2 patients showed marked improvement, 7 patients showed moderate improvement, 10 patients showed mild improvement and 1 patent showed no improvement in the total number of 20 patients.

Probable mode of Action

Haridra is used since time immemorial in different indications including *Madhumeha.* This drug is used both internally and externally also in healing ulcers due to *Madhumeha. Haridra* has got *Katu, Tikta rasa, Katu vipaka, Ushna veerya and Ruksha guna*(5). The therapeutic action of this drug in the management of the *Prameha* cannot be explained through the *Rasapanchaka* only but possible through *Prabhava.* Useful part of *Haridra* is Driedrhizome which is used clinically (6). *Haridra* contains curcumin, curcuminoids, other volatile oils and some coloring substances (7).Many modern research workers from different countries including institutes in India have reported about its hypoglycemic property in Type 2 diabetes.

Aamalaki is used extensively for many centuries as a household remedy for many ailments and also scientifically for its action on *Madhumeha*, which is due to its *Rasayana* property. This drug *Aamalaki* has got five *Rasas* except *Lavana rasa* but predominated by *Amla rasa*. The part used in this plant is its fruit rind. It has *Guru, Ruksha gunas, Madhura vipaka* and *Seetha veerya*(8). Chemically, *Aamalaki* contains many water-soluble tannins like Emblicannins, which are supposed to be the main active principles, behind decreasing the cellular resistance to insulin. The controversy of the

presence of ascorbic acid and vitamin 'c' did not lessen its popular utility. Undoubtedly, *Aamalaki* is proved to be quite effective both experimentally and clinically as a promising hypoglycemic drug (9).

Daruharidra has been mentioned in context of Madhumeha treatment by *Charaka*, *Susruta, Astang Sangraha* and Later on *Dhanvantari Nighantu, Shodal Nighantu, Madanpala Nighantu,Shaligram Nighantu, Bhavaprakasha Nighantu, Kaiyadeva Nighantu* and *Raj Nighantu* have been mentioned. It is also an ingredient of various classical anti-Diabetic formulations. *Raspanchaka* of *Daruharidra* are *–Tikta, Katu Rasa, Laghu, Ruksha Guna, Ushna Virya* , *Katu Vipaka* (10).*Daruharidra* is acting by its *Raspanchaka*, The *Katu* and *Tikta rasas* pacify or balances the *Bahudrava kapha* and *pitta* respectively, By its *Shoshan* properties it reduce excessive *meda, Kleda and Lasika* etc; *Laghu, Ruksha guna* helps to normalize *bahudrava kapha* and indirectly stimulate *Jatharagni* and *Dhatwagni.*The *Ushna Veerya* further helps to bring vitiated *Kapha* and *Vata Doshas* to normal condition and stimulate *Jatharagni* as well as *Dhatwagni*. So in this way the *Rasapanchaka* of the *Daruharidra* normalizes the vitiated *Kapha-Pitta – Vata, Dushya and* Destructs the *Samprapti.*

Regarding the identity of *Daruharidra*, two plant spices are extensively used in the northern and southern parts of India. They are *Berberis aristata* D.C. and *Coscinium fenestratum* colebr. Surprisingly both the drugs have got common chemical constituents like Berberine and both are almost equally efficacious in the management of Diabetes mellitus.

Conclusion

Combination of *Aamalaki*, *Haridra* and *Daruharidra* clearly exhibited the anti-diabetic activity. They are useful as individual ingredients also.

After completing the duration of treatment, it was found that the compound preparation of *Aamalaki, Haridra* and north Indian market drug of *Daruharidra* showed the highest significant activity in reducing the blood sugar levels and the intensity of clinical symptoms in comparison with the South Indian market drug of *Daruharidra.*

As a sample study is very small it requires a larger group of patients for further evaluation.

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