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A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF *NIMBA CHURNA* AND *KARVELLAKA CHURNA* IN THE MANAGEMENT OF *MADHUMEHA* (DIABETES MELLITUS)

[1]*Dr. Priya Singh, [2]Dr. P. Sai Sudhakar and [3]Dr. T. Bullaiah

[1]Final Year PG Scholar, Dept of Kayachikitsa, Dr. N.R.S. Government Ayurvedic College, Vijayawada.

[2]Principal & HOD, Department of Kayachikitsa, Dr. N.R.S. Government Ayurvedic College, Vijayawada.

[3]Professor, Department of Kayachikitsa, Dr. N.R.S. Government Ayurvedic College, Vijayawada.

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***Corresponding Author**
Dr. Priya Singh
Final Year PG Scholar, Dept of Kayachikitsa, Dr. N.R.S. Government Ayurvedic College, Vijayawada.

ABSTRACT

Introduction: Diabetes is a major health issue that has reached a burden on the heath system. It is essential to find the solution of diabetes by using the Ayurveda modalities. The selected drugs *Nimba Churna* and the *Karvellaka Churna* aim to have the potential action that pacify the *kapha-pitta dosha* in the body and can be used for the long-term period. **Methods:** This study was an open labelled, Interventional type, Randomized controlled, comparative study. Patients having the fasting blood glucose level between 110-200 mg/dl and post-prandial blood glucose level 140-250 mg/dl, HbA1c 6.0%-9.0% were randomly divided into the two groups as per the inclusion and exclusion criteria, with each group having 30 individuals. Patients were assessed at 15th, 30th and 45th day until the completion of the trial. Subjective as well as objective criteria were applied for the both the groups. **Result:** Both the groups showed statistically highly significant improvement in the subjective as well as the objective parameters. **Conclusions:** *Nimba churna* has shown better results than the *Karavellaka churna*.

KEYWORDS: *Madhumeha*, diabetes, Ayurveda, *Nimba Churna, Karavellaka Churna*.

INTRODUCTION

Diabetes is a major health issue that has reached a burden on the heath system. Estimation of diabetes by the International Diabetes Federation 2019 reports that India is the home to 77 million diabetes individuals projected to grow up to 147.2 million by 2045.[1]

Diabetes mellitus is a group of common metabolic disorders that share the phenotype of hyperglycemia.[2] Depending on the etiology of diabetes mellitus, factors contributing to hyperglycemia include reduced insulin secretion, increased insulin resistance leading to decreased glucose utilization.[3] Diabetes leads to the many complications such as retinopathy, neuropathy, diabetic foot & many health disorders.[4] Hence, need of the hour is a holistic approach of management. It is essential to prevent and manage *Madhumeha* (diabetes) with ayurvedic measures for long term benefit of an individual.

In Ayurveda, the term diabetes can be correlated to the *Madhumeha* which is a subtype of *Prameha*. It is said to be occurs due to the lazy lifestyle, excessive sleep, excessive consumption of dairy products, sugar products and meat of animals containing heavy fat. *Madhumeha* causes due to the predominance of the *Kapha dosha*. In the respective comparative study, *Nimba Churna*[5] and the *Karvellaka Churna*[6] have the potential action to pacify the *kapha-pitta dosha* in the body and can be used for the long term.

OBJECTIVE

On the basis of the clinical symptom of the *Madhumeha*, drugs were selected to evaluate the comparative effect of *Nimba churna* and *Karvellaka churna* in the management of the Diabetes Mellitus.

METHODOLOGY

Study design

This was an open labelled, Interventional type, Randomized controlled, comparative study. Only those patients affected with diabetes mellitus with the increased fasting blood glucose level between 110-200 mg/dl and post-prandial blood glucose level 140-250 mg/dl, HbA1c 6.0%-9.0% were randomly divided into the two groups as per the inclusion and exclusion criteria, with each group having 30 individuals. Random allocation sequence was generated by using a computer programme that generates the random sequence. All the individuals had given written consent prior to commencement of the trial.

Inclusion criteria

Patients of Diabetes mellitus between the age group of 30-65 years irrespective of the gender and with the fasting blood glucose level 110-200 mg/dl and post-prandial blood glucose level 140-250 mg/dl, HbA1c 6.0%-9.0% were included in the study.

Exclusion criteria

Patients suffering from emergency cases in diabetic mellitus; Pregnant women and lactating mothers; with type-1 Diabetes Mellitus; with severe diabetic complications such as nephropathy, retinopathy, cardiac disease, foot ulcer, diabetic gangrene; with other chronic illness like tuberculosis, bronchial asthma, chronic renal failure, hepatitis and other systemic disorders; and patients of the age below 30 years and above 65 years were excluded from the study.

MATERIALS

Sample size

A total of 60 patients were registered with 0 dropouts. All patients had completed the treatment.

Method of Preparation of drugs

In *Nimba Churna*, stem bark of *Nimba* was taken and prepared it in *Yavakuta* form. In *Karavellaka Churna*, fruit of *Karavellaka* was taken and prepared it in the *Yavakuta* form. All the medicine were prepared in the pharmacy.

Posology

In group A, the trial drug was *Nimba Churna*.[7] The dose of the Churna was 3-gram with the lukewarm water. In group B, the trial drug was *Karvellaka Churna*, 3 gram with lukewarm water.[8] The time of administration was before the food in the morning and evening. The duration of the therapy was for 45 days.

Ethical approval

The plan of the research study was approved by the university under registration no. A201010101.

Criteria for assessment

Following parameters were assessed before treatment and 45 days after the completion of the treatment with subjective parameters as *Prabhuta mutrata, Avila mutrata, Pipasa adhikya,*

Kshudha adhikya, Sweda adhikya, Hastapada daha, Daurbalya, Nidra adhikya, alasya and objective parameters, i.e., Fasting blood glucose, Post prandial blood glucose, HBA1c and Glucose urine. Patients were assessed at 15th, 30th and 45th day until the completion of the trial.

Statistical analysis

For comparison both the group A and group B, paired t-test was used to check the result of intervention in subjective criteria as well as the objective criteria. SPSS software was used on data obtained by various parameters, results were calculated in terms of mean, standard deviation (SD) and Standard error etc.

RESULTS

Result of Subjective parameter in Group A

In Group A, patients were treated with *Nimba Churna* showed highly significant results (P< 0.01, P< 0.001) in following subjective parameters *prabhuta mutrata, avila mutrata, pipasa adhikya, kshudha adhikya, sweda adhikya, hastapada daha, daurbalya, nidradhikya, alasya* with % relief 36.26%, 51.09%, 62.40%, 51.81%, 54.79%, 58.25%, 60.83%, 63% and 75.43%. [Table 1]

Result of Subjective parameter in Group B

In Group B, patients were treated with *Karavellaka Churna* showed highly significant results (P< 0.001) in following subjective parameters *prabhuta mutrata, avila mutrata, pipasa adhikya, kshudha adhikya, sweda adhikya, hastapada daha, daurbalya, nidradhikya, alasya* with % relief 35%, 52.28%, 48.46%, 54.47%, 52.38%, 60.91%, 36.75%, 57.47%, 57.50%. [Table 1]

Table 1: Effect of intervention over the subjective parameters.

Subjective Parameters	Group	Mean		Mean diff.	% Relief	SD		SE		t-value	*P*	*S*
		BT	AT			BT	AT	BT	AT			
Prabhuta Mutrata	A	1.93	1.23	0.70	36.26	0.74	7.77	0.14	0.14	7.17	< 0.001	HS
	B	1.80	1.17	0.63	35	0.71	0.83	0.13	0.15	6.24	< 0.001	HS
Avila mutrata	A	1.37	0.67	0.70	51.09	0.67	0.61	0.12	0.11	7.17	< 0.001	HS
	B	1.53	0.73	0.80	52.28	0.63	0.64	0.12	0.12	7.18	< 0.001	HS
Pipasa Adhikya	A	1.33	0.50	0.83	62.40	0.55	0.51	0.10	0.09	8.60	< 0.001	HS
	B	1.30	0.67	0.36	48.46	0.54	0.71	0.10	0.13	6.24	< 0.001	HS
Kshudha Adhikya	A	1.10	0.53	0.57	51.81	0.66	0.57	0.11	6.16	6.16	< 0.001	HS
	B	1.23	0.57	0.67	54.47	0.73	0.63	0.13	0.11	6.02	< 0.001	HS
Sweda	A	0.73	0.33	0.40	54.79	0.74	0.55	0.14	0.10	4.40	< 0.001	HS

adhikya	B	0.63	0.30	0.33	52.38	0.62	0.47	0.11	0.09	3.81	< 0.001	HS
Daurbalya	A	1.20	0.47	0.73	60.83	0.71	0.51	0.13	0.09	7.71	< 0.001	HS
	B	0.87	0.33	0.53	60.91	0.68	0.48	0.12	0.09	5.76	< 0.001	HS
Hasta padadaha	A	1.03	0.43	0.60	58.23	0.67	0.57	0.12	0.10	6.60	< 0.001	HS
	B	1.17	0.73	0.43	36.75	0.87	0.79	0.16	0.14	4.76	< 0.001	HS
Nidradhikya	A	1.00	0.37	0.63	63	0.70	0.49	0.13	0.09	6.24	< 0.001	HS
	B	0.87	0.37	0.50	57.47	0.68	0.56	0.12	0.10	5.39	< 0.001	HS
Alasya	A	0.57	0.13	0.43	75.43	0.68	0.35	0.12	0..6	4.71	< 0.001	HS
	B	0.40	0.17	0.23	57.50	0.56	0.38	0.10	0.07	2.97	< 0.001	HS

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error, NS: Non-significant, HS: Highly significant, S: Significant.

Result of objective parameter in Group A

Fasting Blood glucose level

At baseline, the mean value of FBG was 169, SD± 19.9, After 45 days of intervention, the mean value was 149, SD± 22.3 which indicated highly significant result (P<0.001) with 11.83% relief.

PPBG

At baseline, the mean value of PPBG was 212, SD± 24.3, After 45 days of intervention, the mean value was 176, SD± 27.4 which indicated highly significant result (P<0.001) with 17.14% relief.

HBA1C

At baseline, the mean value of HBA1C was 7.33, SD±0.57, After 45 days of intervention, the mean value was 7.18, SD± 0.59 which indicated highly significant result (P<0.001) with 1.90% relief.

Urine Glucose

At baseline, the mean value of urine glucose was 1.4, SD±0.81, After 45 days of intervention, the mean value was 0.7, SD± 0.7 which indicated highly significant result (P<0.001) with 50% relief. [Table 2]

Result of Objective parameter in Group B

Fasting Blood glucose level

At baseline, the mean value of FBG was 166, SD± 18.7, After 45 days of intervention, the mean value was 153, SD± 18.7 which indicated highly significant result (P<0.001) with 7.22% relief.

PPBG

At baseline, the mean value of PPBG was 234, SD± 29.7, After 45 days of intervention, the mean value 199, SD± 30.4 which indicated highly significant result (P<0.001) with 14.95 % relief.

HBA1C

At baseline, the mean value of HBA1C was 7.2, SD± 0.64, After 45 days of intervention, the mean value was which indicated highly significant result (P<0.001) with 1.38 % relief.

Urine Glucose

At baseline, the mean value of urine glucose was 1.4, SD± 0.8, After 45 days of intervention, the mean value 0.6, SD± 0.6 which indicated highly significant result (P<0.001) with 57.14 % relief. [Table 2]

Table 2: Effect of intervention over the objective parameters

Objective parameter	Group	Mean		Mean diff.	% Relief	SD		SE		t-value	P	S
		BT	AT			BT	AT	BT	AT			
FBG	A	169	149	20	11.83	19.9	22.3	3.6	4.1	12.6	< 0.001	HS
	B	166	153	12.0	7.22	18.7	18.0	3.4	3.3	14.0	< 0.001	HS
PPBG	A	212	176	36	17.14	24.3	27.4	4.4	5	18.2	< 0.001	HS
	B	234	199	35.0	14.95	0.64	30.4	5.4	5.6	15.1	< 0.001	HS
HBA1C	A	7.33	7.18	0.14	1.90	0.57	0.59	0.1	0.1	11	< 0.001	HS
	B	7.25	7.12	0.13	1.77	0.64	0.65	0.1	0.2	6.7	< 0.001	HS
UG	A	1.4	0.7	0.7	50	0.81	0.7	0.1	0.12	7.16	< 0.001	HS
	B	1.4	0.6	0.8	57.14	0.8	0.6	0.1	0.1	6.1	< 0.001	HS

FBG: Fasting Blood Glucose level, PPBG: Post prandial blood glucose level, UG: Urine glucose level, BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error, NS: Non-significant, HS: Highly significant, S: Significant.

DISCUSSION ON OBSERVATION

In this study, 66.67% patients were male. According to the Ayurveda, male patients tend to be more prone for diabetes as compared to that of females because of the work-related stress and the sedentary lifestyle.[9] 50% belonged to the age group 46-55 years. 63.33% patients were found to be non-vegetarian. Non-vegetarian food is considered to be one of the main cause of diabetes. 60% obese patients found to have the diabetes. 60% patients found the cause *diwaswapna*. 46% patients found of *vata-kapha prakriti*. 46.7% patients found the *vishama agni* (taking diet before or after the actual time for meal). 53.33% patients found *krira kostha* specify the aggravation of the *vata dosha* in the body.

Discussion on subjective parameter

Madhumeha considered as one of the eight disease which is life threatening. It belongs to the category of the *vataja prameha*. Causative factors which increase the *kapha* and *meda* in the body produces the *prameha*. Different causes mentioned in Ayurveda compendium are *adhyashana, guru, snigdha, madhura, dadhi, gramya* and the *anupa mamsa.* Pathogenesis of the *Madhumeha* involves *kapha-medovarodhaka nidana* causing the obstruction to the flow of the vata responsible for the production of the *Avarana* type of *Madhumeha*. In the pathogenesis of *Avaranajanya madhumeha, kapha* and *pitta* are the main *dosha*. *Dushya* are *meda dhatu* and *kleda*. It results into the various symptoms such as *prabhuta mutrata, Avila mutrata, pipasa adhikya, kshudha adhikya, sweda adhikya, hastapada daha, daurbalya* and *nidra adhikya*.

So here the selected drugs *Nimba churna* and the *Karavellaka churna* have the *kaphahara* properties with the aim to cure the *Madhumeha* as the *Kapha-pardhana vyadhi*. *Nimba churna* owing to the *tikta, kashaya rasa, laghu guna, rukshana* effect. *Karavellaka* has *tikta, katu rasa, laghu, ruksha guna* and *ushna virya*.

Discussion on objective parameter

As both the selected drugs having the *kaphahara* and anti-diabetic property. Both the drugs showed highly significant results in their *kleda, medohara* properties. *Nimba churna* showed 11.83% improvement in fasting blood glucose level, 17.14% improvement in the post-prandial blood glucose level. 1.90% improvement in HBA1C and 50% improvement in the levels of urine glucose. In a pharmacological study, Azadirechta indica bark extract showed decrease in the blood glucose level. *Karvellaka* showed 7.22% improvement in fasting blood glucose level, 14.95% improvement in the post-prandial blood glucose level. 1.79% improvement in HBA1C and 57.14% improvement in the levels of urine glucose. *Nimba* has anti-inflammatory, hypoglycemic, antipyretic, diuretic, anti-gastric ulcer, antibacterial, antifungal, and spermicidal property.[10] *Karavellaka* has It has anti-diabetic, antiviral, antitumor, antiulcer, anti-inflammatory, hypocholesterolemia, hypotriglyceridemic, hypotensive and immunostimulant properties.[11]

CONCLUSION

Although there is no description of Diabetes in Ayurveda, it is found to possess a strong correlation with *Madhumeha*. Both the groups showed statistically highly significant improvement in *prabhuta mutrata, avila mutrata, pipasa adhikya, kshudha adhikya, sweda*

adhikya, hastapada daha, daurbalya, nidradhikya, alasya but better than *Karavellak Churna* group. In the objective parameters fasting blood glucose, post-prandial blood glucose, HBA1C and urine glucose showed highly significant results. On the basis of the result, we can conclude that *Nimba churna* has shown better results than the *Karavellaka churna*.

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REFERENCES

1. Ogurtsova K, Guariguata L, Barengo NC, Ruiz PL, Sacre JW, Karuranga S, Sun H, Boyko EJ, Magliano DJ. IDF diabetes Atlas: Global estimates of undiagnosed diabetes in adults for 2021. Diabetes research and clinical practice, 2022 Jan 1; 183: 109118.
2. Lebovitz, H. E. (2001). Diagnosis, classification, and pathogenesis of diabetes mellitus. *Journal of Clinical Psychiatry*, *62*(27): 5-9.
3. Petersen, K. F., & Shulman, G. I. (2006). Etiology of insulin resistance. *The American journal of medicine*, *119*(5): S10-S16.
4. CLARK JR, Charles M.; LEE, D. Anthony. Prevention and treatment of the complications of diabetes mellitus. *New England journal of medicine*, 1995; 332.18: 1210-1217.
5. Bhavaprakash, Bhavaprakash samhita, Bhrahma Shankar S., editor., Guduchyadi Varga/95-96. 9th ed. Chaukhamba Sanskrit Bhavan, 1999; 328.
6. Bhavaprakash, Bhavaprakash samhita, Bhrahma Shankar S., editor., Shaka Varga /63. 9th ed. Chaukhamba Sanskrit Bhavan, 1999; 683.
7. Bhavaprakash, Bhavaprakash samhita, Bhrahma Shankar S., editor., Guduchyadi Varga/95-96. 9th ed. Chaukhamba Sanskrit Bhavan, 1999; 328.
8. Bhavaprakash, Bhavaprakash samhita, Bhrahma Shankar S., editor., Shaka Varga /63. 9th ed. Chaukhamba Sanskrit Bhavan, 1999; 683.
9. NYBERG, Solja T., et al. Job strain and cardiovascular disease risk factors: meta-analysis of individual-participant data from 47,000 men and women. *PloS one*, 2013, 8.6: e67323.
10. BHOWMIK, Debjit, et al. Herbal remedies of Azadirachta indica and its medicinal application. *J Chem Pharm Res*, 2010; 2.1: 62-72.
11. Grover JK, Yadav SP (2004). Pharmacological actions and potential uses of Momordica charantia: a review. Journal of Ethnopharmacology, 2004; 93: 123–132.