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A Comparative Clinical Study of *Phalatrikadi Kwath* and *Nyagrodhadi Kwath* in *Madhumeha* w.s.r.t. Diabetes Mellitus.

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ABSTRACT:

Introduction: In modern era changing lifestyle like *alasya*, *divaswanpa*, environmental changes, faulty eating habits like *madhur – guru ahara* etc are leading to Diabetes mellitus. Diabetes mellitus is metabolic disorder of multiple etiology characterized by Hyperglycemia, with disturbance of carbohydrate, fat, protein metabolism that can lead to serious complications such as cardiovascular disease, diabetic retinopathy and Nephropathy etc. Because of complication of allopathic treatment peoples are preferring ayurvedic treatment. For treatment here attempt is being made with *kwath* preparation as usually *ghruta* preparation is widely used.

Aim and objectives: 1) To study effect of *phalatrikadi kwath* and *Nyagrodhadi kwath* in *madhumeha*. 2) To compare effect of *phalatrikadi kwath* and *Nyagrodhadi kwath* in *madhumeha*.

Material and method: In this study 40 patients were selected and divided into 2 group with 20 patients each. Group A was administered with *phalatrikadi kwath* and group B with *Nyagrodhadi kwath* 40ml respectively for 28 days. After treatment results were assessed on basis of subjective and objective criteria by using unpaired T test.

Observation and result: Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with unpaired t test. The test shows that the treatment is significant in Group B when compared to Group A. Group A overall result is 85.88% and Group B overall result is 92.49%

Conclusion: The overall study reveals that group B *Nyagrodhadi kwath* showed more efficacy.

Keywords: *Madhumeha*, *Prameha*, Diabetes mellitus type 2, *Phalatrikadi kwath*, *Nyagrodhadi kwath*.

INTRODUCTION

In modern era due to intake of fast food, sedentary life style, excessive sleep(*divaswapna*), irregular meal pattern, anxiety, unhealthy hectic schedules which causes stress.

Due to all these *kapha* in body increases leading to *Madhumeha*. *Madhumeha* is caused due to intake of *guru*, *snigdha*, *amla*, *lavan rasa ahar* in excess quantity, intake



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of newly harvested food, excessive sleep, avoidance of exercise, and excessive thinking, , *mruja varjana* (not doing of any purification procedure), due to all these factors *kapha*, *pitta*, *vata* increases and causes *madhumeha*. It mainly affects *medovaha srotas* along with *mamsavaha srotas*, *udakavaha srotas*, *mutravaha srotas*. All *tridoshas* get vitiated but predominantly *vata* get vitiated. The *vata* along with *ojas* goes towards *basti pradesh* which leads to *madhumeha*. These may produce symptoms like thirst, dry mouth, polyuria, nocturia, tiredness, fatigue, lethargy. The incidence of diabetes type-2 is rising rapidly globally. It is estimated that 366 million people had diabetes in 2011 which may reach 552 million by 2030. The main aim of Ayurvedic treatment is not only cure the disease but also treat the root cause of disease. Many studies have been conducted in the efficacy of ayurvedic drugs in *madhumeha* which have proved to be effective. Classical and proprietary medicine are widely used for management of *madhumeha* because of good control and less side effects.

AIM AND OBJECTIVES

1. To study about *madhumeha* and Diabetes mellitus comparatively.
2. To study effect of *phalatrikadi kwath* in *madhumeha*.
3. To study effect of *Nyagrodhadi kwath* in *madhumeha*.
4. To compare the effect of *phalatrikadi kwath* and *Nyagrodhadi kwath* in *madhumeha*.

MATERIAL AND METHOD

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Methods of collection of data: It is a clinical comparative study, where 40 patients of *madhumeha* will be selected & treated with medicine for 28 days. The sign and symptoms will be recorded as per case pro-forma designed for the study before and after treatment with 2 follow up of 14 days respectively.

Group A: Patient will be administered with *phalatrikadi kwath* (40 ml /twice a day after meal)

Group B: Patient will be administered with *nyagrodhadi kwath* (40 ml /twice a day after meal)

Inclusion criteria:

1. Patient between age group of 25 to 60 years of either gender.

2. Patients with clinical signs and symptoms of *madhumeha* (*prabhut vilay mutrata, trushna, hasta padatala daha, klama, madhuratva in mutrata, deha chikkanata, swas asyata, dantadiham mala sanchaym, jatil bhava kesheshu*). Though many of this are *poorvarupa*, if they are increased they can be considered as *rupas*.
3. Patients who are already diagnosed or having above *madhumeha* signs and symptoms for more than 6 months.

Exclusion criteria:

1. Patients of age group other than 25 to 60 years and pregnant ladies.
2. Patients who are diagnosed or having above *madhumeha* signs and symptoms for less than 6 months,
3. Patients who are known case of any other major illness like hypertension, heart disease, other endocrine disorders like thyroid disorder, severe systemic disorders .etc.
4. Patients receiving any other treatment or any drugs like steroids NSAIDS, AKT, and ART etc.

Study design:

40 Patients of *madhumeha* who fulfill the inclusion criteria will be selected and randomly assigned into 2 groups, each comprising of 20 patients for duration of 28 days with 2 follow up of 14 days respectively.

Drug review:

The main tool of physician to cure illness is nothing but *dravyas*. It is the vested duty of each and every scholar to update the ancient therapeutics measures which are given in ayurvedic classics and to search new drugs and formulation within ayurvedic theoretical essence. So it is work to select a drug or compound which is more suitable for a particular clinical condition unless the scholar is well studied so here it is humble attempt to study comparative study of *phalatrikadi kwath* and *nyagrodhadi kwath* and the detail study of these is given below. *Phalatrikadi kwath* consist of *triphala* which is *kapha pitta shamak, pramehahara*, it possess antidiabetic and antioxidant property which reduces oxidative stress and alleviate diabetic complication. *Mustaka* is *aampachak, deepan* that reduces symptoms caused by *aam* which help to digest *aam*. *Indrayava* is purgative, it removes unwanted *aamdosha* and mala from body. These all combine drugs possess the action by reducing *aam* by *shaman* and *shodhan* which does not cause *doshaprakopa*. *Anupan* of *phalatrikadi kwath* is *madhu*. *Nyagrodhadi kwath* contains *udumbar, ashwath, amara*,

jambu, arjuna, paribhadra, meshashrunji, chitraka, madhuka, beejak, patola etc along with all these drugs prepared *kwath* having *katu kashya rasa, laghu ruksha tikshana guna, virya ushna* and *katu vipaka* which alleviate *kapha* and *pitta* also help to remove obstruction of *vata*. As it is *grahi* reduces symptoms like *prabhutavilay mutrata* and reduces *karapadataladaha*.

Criteria for assessment:

After the completion of the treatment, the results were assessed by adopting the following criteria:

- Improvement in signs and symptoms of disease on the basis of symptoms score.
- Fasting Blood Sugar and Post Prandial Blood Sugar levels
- Urine Routine the patient were examined weekly and the changes observed in the signs and symptoms were assessed by adopting suitable scoring method and the objective signs by using appropriate clinical tools. The detail assessment of clinical signs and symptoms are discussed below:

1) *Prabhuta Mutrata*: (Polyuria)

Criteria for assessment (Table no 01)

Statistical analysis:

Comparative analysis of overall effect of the treatment in both group was done by statistically with unpaired “t” test. The test shows that treatment in group B is effective than treatment in group A. Group A overall result is 85.88% and Group B overall result is 92.49%.

Assessment of overall effect of therapy:

- Control of the disease: Up to 5% complete relief in signs and symptoms >35mg /dl reduction in postprandial blood sugar level.
- Markedly Improved: Up to 75% relief in signs and symptoms and 25 mg reduction in postprandial blood sugar level.

Therapeutic effect of trial drugs:

40 patient of *madhumeha* were treated in two groups. 20 patients were treated in group A (*phalatrikadi kwath*) with 40ml *kwath* twice a day after meal while 20 patients treated in group B (*Nyagrodhadi Kwath*) with 40 ml *kwath* twice a day after meal.

OBSERVATION AND RESULTS

Comparative results of Group-A and Group-B (Table no

02):Table no 03 Comparative results of Group A and Group B with Mean Difference:

Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with unpaired t test. The test shows that the treatment is significant in Group B when compared to Group A. Group A overall result is 85.88% and Group B overall result is 92.49%
Chart no 01-Comparative results of Group-A and Group-B

DISCUSSION

- Age: In the present study 55% patients were from the age group of 41-50 year revealing that individuals are more affected by type-2 diabetes mellitus after 40 mostly due to stress, faulty eating habits, changing lifestyle etc. are common cause in this age group.
- Gender: 75% male remaining 25% are female.
- Religion: Majority of patients 90% are belongs the Hindu community.
- Occupation: 50% farmers while remaining are working women and housewife.
- Prakruti*: 80% *vata kaphaja prakruti*, 10% *pitta kapha prakruti* and 5% are having *vata pitta prakruti*.
- Akruti*: 60% patients are having *sthula prakruti* and 30% are *madhyam prakruti*. Asian Indians are having greater degree of central obesity are more prone to diabetes and related metabolic abnormalities, In *samhita sthoulya* has been said to be disposing factor.
- Agni: 45% of patient are having *vishamagni*, 35% *madhyam agni*, 15% are having *tikshnagni* remaining 5% having *mandagni*.
- Kostha*: 50% are having *krura kostha*, 40% *madhyam kostha*, 10% are having *mrudu kostha*.

Effect of therapy on subjective criteria (Table no 04):

Overall effect of therapy: Both *kwaths* have effect on *madhumeha*. As compared to *phalatrikadi kwath* *Nyagrodhadi kwath* have shown better effect on the patients of *madhumeha* by *samprapti bhagna* of disease with significant reduction in the symptoms of *madhumeha* like *prabhut vilaymutrata, trushna, karapadyosuptadaha, mukhtalukantashosha, madhuryam mukha asyata*. It has also show changes in biochemical parameters like fasting blood sugar level, post prandial blood sugar level and urine sugar level. The study has shown fairly good changes in blood sugar level and urine sugar level throughout follow up for 28 days but extended follow up is needed to lower down the dose conventional hypoglycemic agents and to

prevent the complication of Diabetes Mellitus type 2.

CONCLUSION

A scientific discussion on the study gives rise to fruitful conclusion. Ayurveda is the science which is diagnosed and manage *madhumeha*. *Madhumeha* correlate with Type 2 diabetes mellitus. *Bruhatrayis* have explained *madhumeha* in detail. *Madhumeha* is mainly caused due to sedentary lifestyle, not doing of any exercise, due to excessive stress, consumption of fast food, all these are causative factor for *madhumeha*. As *madhumeha* is caused due to adaptation of *hetus* so *hetuviparita chikitsa* should be done. On the basis of *agni* 45% patient are having *Vishamagni*. 50% of patients are having *krura kostha*. 85% of patients are having *Vishamashana*. Maximum no patients are having *chintadhikya*. Out of two group's group B *Nyagrodhadi Kwath* is having maximum effect on *prabhutmutrata*. There is significant reduction in mean score statistically $p < 0.05$. *Jalapana vidhi viruddha hetus* like *ushapana* (55%), *Nishapana* (45%), *Bhojanottara jalapna* (80%). *Vishay hetus* like *diwaswapna* (80%), *ratrijagarana* (60%), *avyayam* (95%), *Manasika hetu* like *chinta*. all these findings indicate *santarpanjanya nimittaja* and *apatyanimittaja prameha*. Group B has highly significant effect on *trushna* as compared to group A. In this study Group B is having highly significant changes in objective parameters like blood sugar level (< 0.05) and post prandial blood sugar level as compared with group A. In this study Group B (*Nyagrodhadi Kwath*) shows highly significant results in reduction of the subjective parameters like quality of urine *Prabhutamutrata*, *Daurbalya*, *Mutramadhurya* symptoms ($p < 0.05$) than in Group A. The Present study was carried out on small sample size for limited period. It shows encouraging results in patients of *madhumeha*. So further study is needed in modification of groups. The comparative analysis of the overall effect of the treatment in both the groups shows that treatment is more significant in Group B than in Group A as Group A overall result is 85.88% and Group B overall result is 92.49%.

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Prabhuta Mutrata: (Polyuria)

Quantity of urine:	Gradation
➤ 1.50 to 2.00	0
➤ 2.00to2.50	1
➤ 2.50to3.00	2
➤ 3.00and onwards	3
Frequency of Urine:	
➤ 3-6 times per day rarely at night	0
➤ 6-9 times per day 0-2 times per night	1
➤ 9-12times per day 2-4 times per night	2
➤ More than 12 times per day ,more than 4 times per night	3

Criteria for assessment (Table no 01)

Criteria for assessment	Gradation			
	Regular usual	Slightly Increased	Moderately Increased	Markedly Increased
2) <i>Trushna</i>	0	1	2	3
3) <i>Kara Padayo supta daha</i>	0	1	2	3
4) <i>Mukh talu kantha shosha</i>	0	1	2	3
5) <i>Madhuryam mukha asyata</i>	0	1	2	3

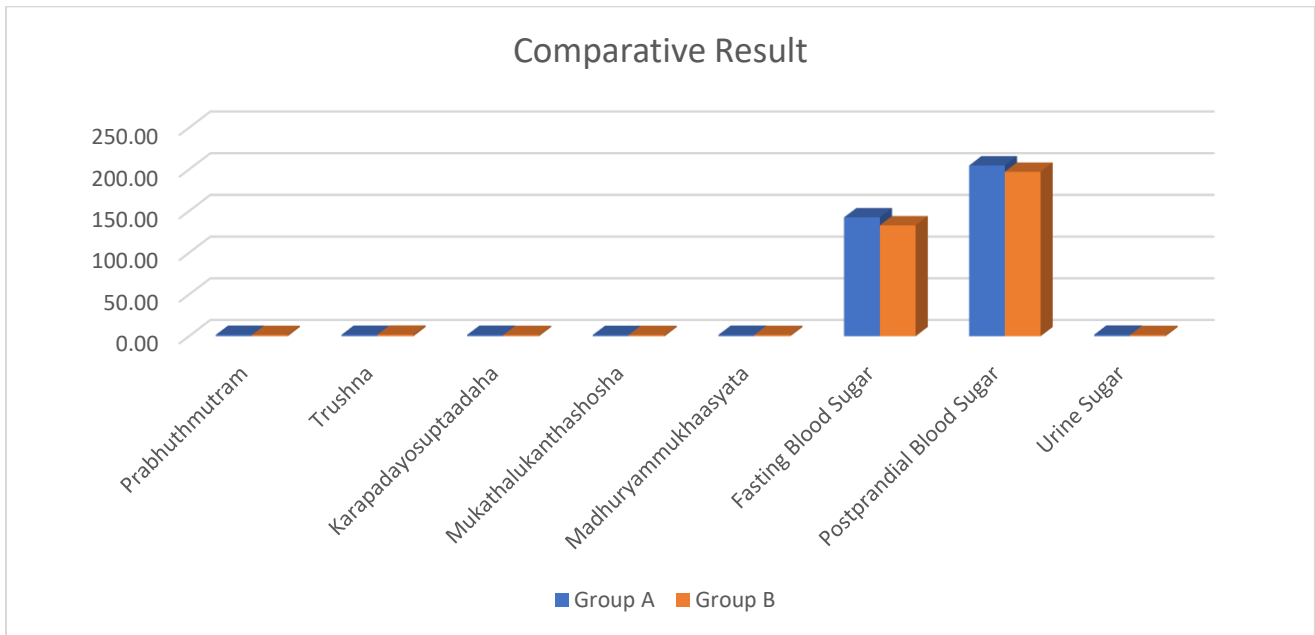
Comparative results of Group-A and Group-B (Table no 02):

Signs and Symptoms	Group A (Mean Score)	Group B (Mean Score)	SE	T Value	P Value
<i>Prabhuthmutram</i>	1.76	1.59	0.10	1.61	<0.05
<i>Trushna</i>	1.75	1.89	0.16	-1.04	>0.05
<i>Karapadayosuptaadaha</i>	1.71	1.50	0.10	2.00	<0.05
<i>Mukathalukanthashosha</i>	1.51	1.49	0.15	0.20	>0.05
<i>Madhuryammukhaasyata</i>	1.70	1.58	0.14	0.94	>0.05
Fasting Blood Sugar	142.64	133.03	4.34	2.57	<0.05
Postprandial Blood Sugar	204.84	197.25	5.62	1.37	>0.05
Urine Sugar	1.84	1.49	0.10	3.48	<0.05

Table no 03 Comparative results of Group A and Group B with Mean Difference:

Group A	Group B	Mean Difference	SE (±)	T value	P value
85.88	92.49	6.61	1.92	3.48	<0.05

Chart no 01-Comparative results of Group-A and Group-B



Effect of therapy on subjective criteria (Table no 04):

Subjective criteria	GROUP A mean score			GROUP B mean score		
	before treatment	after treatment	% improvement	before treatment	after treatment	% improvement
Effect on <i>prabhutmutrata</i> (20 patient)	2.90	0.30	80	3.00	1.15	96.67
Effect on <i>Trushna</i> (20 patient)	2.80	1.45	80.70	2.85	0.55	82
Effect on <i>karapadayosuptadaha</i>	3.00	1.25	86.67	2.90	0.05	98.28
Effect on <i>Mukhatalukantashosha</i>	2.80	0.35	87.50	2.70	1.10	94.44
Effect on <i>Madhuryammukhaasyata</i>	2.75	0.40	85.45	2.75	1.20	90.91
Effect on fasting blood sugar	161	138	26.50	153	125	25
Effect on postprandial Blood sugar	249	196	43.42	236	197	41.31
Effect on Urine Sugar of <i>Madhumeha</i>	3.25	1.90	90.77	2.95	1.00	100