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A Comparative Clinical Study on the Effect of *Amalakyadi Kalka Shirolepa* in Diabetes mellitus with and without History of Stress

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ABSTRACT

INTRODUCTION

In the modern era of stressful life with unlawful food habits and lifestyle has led to the manifestation of metabolic disorders like Diabetes mellitus, which can be correlated to *Madhumeha*. It is of high concern due to its increased mortality and morbidity. There are different modalities of *chikitsa* in Ayurvedic Panchakarma therapy which are capable of treating the *manas* and *shareera*. *Shirolepa* is one such procedure which holds good in *manoshareeravyadhi*. Here an effort is made to study the effect of *amalkyadi kalkashirolepa* in patients of diabetes mellitus with and without history of stress.

MATERIALS AND METHODS

A total of 20 patients were selected and divided into two groups, group A consisted of patients with history of stress and group B consisted of patients with no history of stress. For both groups *amalakyadi kalka shirolepa* was given.

RESULTS

Both the groups showed good improvement but group A had given better results.

DISCUSSION AND CONCLUSION

Shirolepa has shown good results in both groups but it has got better results when stress factor is involved in the pathology of the disease.

KEYWORDS

Madhumeha, Shirolepa, Diabetes mellitus, Amalakyadi kalka

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INTRODUCTION

Diabetes mellitus may be a group of metabolic disorders characterized by high blood glucose levels over a protracted period. Symptoms of high blood sugar include frequent urination, increased thirst and increased hunger[1]. Inspite of many advanced medicines, medical facilities and pathological investigations, the management of Diabetes mellitus still remains unsatisfactory. Studies have shown that keeping mind calm and having good sleep plays a significant role in controlling blood glucose levels. According to WHO, approximately 220 million people worldwide have type 2 Diabetes mellitus[2]. Since the 17th century, it has been suggested that emotional stress play a role in the etiology of type 2 Diabetes mellitus. So far, review studies have mainly focused on depression as a risk factor for the development of the disease, but also general emotional stress and anxiety, sleeping problems, anger and hostility are associated with an increased risk. Diabetes mellitus can be correlated to *Madhumeha* which is caused by various *manasika nidanas* also like *Krodha, shoka, udvega etc. Shirolepa* is one of the *upakramas* mentioned in *keraliya panchakarma* which is capable of treating both *mano* and *shareerika dosha*. Even though many studies on *takradhara* in *madhumeha* and its complications have been done, *shirolepa* is having almost the same effect of *takra dhara.* Moreover *shirolepa* is less time consumable, requires minimal manual intervention, and can be adopted at OPD level and no major infrastructure is required. In this study, an effort has been made to compare clinical efficacy of *shirolepa* with *Amalaki* and *Yastimadhu* in patients of Diabetes Mellitus with and without history of stress.

AIMS AND OBJECTIVES

- To assess the effect of *amalakyadi kalka shirolepa* in patients of Diabetes mellitus with history of stress.
- To assess the effect of *amalakyadi kalka shirolepa* in patients of Diabetes mellitus without history of stress.

MATERIALS AND METHODS

For the present study, 20 patients who fulfill the inclusive criteria were randomly selected from the Panchakarma dept OPD and IPD, Shri Jayachamrajendra Institute of Indian Medicine Hospital, Bengaluru-09.

Diagnostic Criteria: Known cases of type 2 DM with and without history of stress.

Inclusion Criteria:

- Diagnosed cases of type 2 Diabetes Mellitus[3].

- Age in between 30-80 years, irrespective of gender.
- HbA1c more than 8%.

Exclusion Criteria:

- Diabetes mellitus type 1[4].
- With any other serious systemic illness.

Duration of Study: 21 days.

Plan of Study: Patients were advised to continue their treatment of Diabetes without interruption. Two groups of 10 patients each were made based on the history of stress. Those with history of stress were taken in group A and others in group B.

Poorvakarma

Preparation of medicine: 10 grams of *yastimadhu kashayachoorna* was boiled with 80ml of milk and 80ml of water till *ksheeravashesha* was obtained. It was then fermented by adding curd, the same was churned into buttermilk by adding equal quantity of water. To this 150gms of deseeded *Amalaki* was added after soaking it overnight in water. Next day morning *takra* along with *Amalaki* was boiled till it became smooth and watery portion got evaporated. After cooling *kalka* was obtained by triturating with pestle and mortar.

Preparation of patient: Hair over the head was trimmed. Before procedure patient was asked to void *vegas* if any.

Pradhana karma-

After *shiro abhyanga, kalka* which was prepared was taken and applied over the scalp starting from the center then applied evenly all over the head of about thickness of 1.5cm. Then leaf of banana was kept over it. Kora cloth strap was tied around the forehead above ears. The procedure was conducted in the morning hours, 30 minutes after waking up.

Paschat karma-

After completion of one *muhurta, kalka* applied over head was removed. Patient was made to wipe head with a towel and advised to take luke warm water head bath. After bath patient was made to wipe head to ensure no moisture was retained. *Rasnadichoorna* was then rubbed over vertex. The patients were advised not to expose to direct sunlight, direct wind, fan, two wheeler travelling.

ASSESSMENT CRITERIA

Subjective Parameter-

1. *Krodha* –

No violent tendencies	0
Violent tendencies rarely	1
Violent and sadistic tendencies often	2
Frequent thought and function of violent and sadistic	3

2. *Shoka-*

No feeling of sorrow	0
Feels sorrow occasionally	1
Feels sorrow often	2
Weeps and feels sorrow frequently	3

3. *Udwega-*

Not present	0
Mild- mentions or acknowledge being fearful and worried on direct questioning.	1

Moderate- volunteerly tells about being anxious and may ask for assurance.	2
Severe- feels panic attacks and may speak of impending death	3
4. Muhur-muhur mutra pravritti –	
Frequency of micturation at night 0-1	0
Frequency of micturation at night 2-3	1
Frequency of micturation at night 4-5	2
Frequency of micturation at night >5	3
5. *Sleep disturbance-*	
No sleep disturbance	0
Difficulty in initiation of sleep	1
Wakefullness during sleep	2
Reduction in sleep hours of less than 6hrs	3

OBSERVATION AND RESULTS

Total 22 patients were registered for the study. Out of that, 20 patients were studied in this trial. 10 patients were in group A while 10 were in B group. In group A and group B, maximum patients were in age group 40- 60 years followed by age 30-40 years. They were 62% and 38% respectively. Among them 65% were males and 35% were females, 82.5% were from middle class. Majority of patients had *alpa nidra pravrutti*. Maximum patients were of *Vata Pitta prakruti* followed by *Kapha Vata prakruti*. They were 55% and 45 % respectively.

The subjective and objective parameter changes in group A and B are shown in table 1,2,3 and 4, respectively. There was statistically highly significant improvement in subjective parameters like *krodha, udwega, muhur muhur mutra pravritti, nidra* and statistically significant improvement of shoka in group A, where stress is major *nidana* for causation of disease.There was statistically significant improvement in *krodha, shoka, udwega* and no statistically significant changes in *muhur muhur mutra pravritti* and *nidra* in group B patients where history of stress was not elicited. Objective parameters like urine sugar showed statistically highly significant improvement where as FBS and PPBS showed statistically significant improvement in group A. FBS showed non significant result but the rest two had statistically significant results in group B. Thus *amalakyadi shirolepa* has got overall good effect in managing *madhumeha* but is more beneficial in patients with history of stress.

DISCUSSION

Madhumeha is one among the *mahavyadhi*, which is considered to be *yapya*[5]. While explaining the *nidanas* for *madhumeha Charaka, Sushrutha* and *Madhavakra* mentioned different *manasika nidanas* like *Krodha, Udwega, Shoka*[6]. Hence it becomes clear that these *hetus* play an important role in *madhumeha*.*Acharyas* have explained *Manasika nidana* as *vishesha nidana* for *pitta* and *vata prameha,*

Table 1 Group A- subjective parameters

PARAMETER	MEAN OF BT-AT	SE	T VALUE	P VALUE	REMARKS
Krodha	0.70	0.153	4.5826	0.0013	Highly significant
Shoka	0.40	0.163	2.4495	0.03	Significant
Udwega	0.60	0.163	3.6742	0.0051	Highly significant
Muhur muhur mutra pravritti	0.70	0.153	4.5826	0.0013	Highly significant
nidra	0.60	0.163	3.6742	0.0051	Highly significant

Table 2 Group B-subjective parameters

PARAMETER	MEAN OF BT-AT	SE	T VALUE	P VALUE	REMARKS
Krodha	0.50	0.167	3.0012	0.015	significant
Shoka	0.50	0.167	3.0012	0.015	Significant
Udwega	0.50	0.167	3.0012	0.015	significant
Muhur muhur mutra pravritti	0.30	0.153	1.9640	0.08	Not significant
nidra	0.30	0.153	1.9640	0.08	Not significant

Table 3 Group A- objective parameters

PARAMETER	BT	AT	% OF IMPROVEMENT	SD	T VALUE	P VALUE	REMARKS
FBS	182.08	160.12	15.81	28.74	2.39	<0.05	Significant
PPBS	269.88	235.28	18.92	40.89	2.44	<0.05	Significant
URINE SUGAR	0.94	0.52	61.70	0.513	3.74	<0.001	Highly significant

Table 4 - Group B- objective parameters

PARAMETER	BT	AT	% OF IMPROVEMENT	SD	T VALUE	P VALUE	REMARKS
FBS	176.08	157.24	12.78	24.14	1.53	>0.05	Not Significant
PPBS	245.32	212.16	16.81	32.51	2.31	<0.05	Significant
URINE SUGAR	0.72	0.52	58.33	0.236	3.62	<0.05	significant

which signifies that it has a major role in progression of *vyadhi*. Diabetes mellitus is a metabolic disorder, due to interference of continuous stress for long duration the disease will result onto uncontrolled diabetes even when on hypoglycaemic drugs, hence the approach towards disease should vary. When stressed, the body prepares itself by ensuring that enough sugar or energy is quickly available. Insulin levels fall, glucagon and epinephrine levels rise, which causes body tissues to be less sensitive to insulin[7]. As a result more glucose is available in blood stream. As the oral medications used for management of psychological condition will further disturb the hormonal integrity of glucose metabolism, thus it becomes a complex issue to manage the stress with diabetes by

using oral medications for stress management.

Cortisol hormone or stress hormone is a glucocorticoid produced from cholesterol in adrenal glands. It is normally released in response to events and circumstances like awakening in the morning, exercising and acute stress. Under stressful conditions, cortisol provides body with glucose by tapping into protein stores via gluconeogenesis in liver. Elevated cortisol over the future consistently produces glucose, resulting in increased blood glucose levels[8]. Application of *shirolepa* helps to reduce cortisol levels by reducing stress and thereby help in regulating blood glucose levels. Thus in this study *amalakyadi shirolepa* is applied in the morning hours around 30minutes after waking up when cortisol levels are generally high in the body.

The presence of heterocyclic organic ring structures in *tila taila* probably facilitate the dissolution and penetration of medicinal substances through the skin.*Amalaki*has *lavana varjitha pancha rasa, rooksha* and *laghu guna, sheeta virya,* best *rasayana, medya* and *paramehaghna.* Active principle in *amalaki* Phylembline has got anti diabetic activity.*Yastimadhu* is *vatapitta shamaka* and has *medya prabhava*. As per *Charaka* it is to be processed with *ksheera* for *medhya karma*.*Takra*contains large amount of lactic acid and acts as probiotic and acts as a good vehicle for transdermal absorption of drugs.

CONCLUSION

Even though, diabetes mellitus is a metabolic disorder, stress plays an important role in progression of disease and thereby early onset of diabetic complications.Management of stress in diabetic patients is equally important along with hypoglycemic drugs to maintain the average blood glucose. As *madhumeha* is *yapya*, the stress management will improve the quality of life and thereby to live diabetes with less or delayed complications.*Amalakyadi shirolepa* is very effective in managing the stress related symptoms and thereby improving the quality of life. However this will not provide permanent cure and it should be adjuvanted with proper diet and exercises.

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