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Research Article

Study to evaluate the add on effect of specific *Yoga* therapy along with
Amalaki Churna in Type 2 Diabetes Mellitus

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Abstract-

The prevalence of Diabetes is rapidly rising all over the globe at an alarming rate. Diabetes Mellitus occurs throughout the world, but it is more common; especially Type-2 Diabetes Mellitus in the developed countries. WHO predicted that at the current rate there will be some 592 million D.M. people by the year 2035. In India, it is estimated that by the year 2017 total number of Diabetic subjects to be around 72.9 and by year 2045 it is further set to rise to 134.3 million (IDF). Various scientific researches showed *Yogasanas* have great potential in the prevention and the control of lifestyle disorders like metabolic syndrome, asthma, cancer, diabetes and its co-morbid conditions like hypertension and dyslipidemia etc. Simultaneously, various Ayurvedic single herbs proved its potential in the control of Diabetes and its complications by their antioxidant properties and *Amalakichurnais* one of them. Thus for the present study

specific yoga therapy and *AmalakiChurna* were selected for the patients of Type 2 Diabetes Mellitus. **Method:** For this study total 60 diagnosed patients of type 2 DM were selected from OPD of Dept. of Kayachikitsa, Panchakarma and Swasthavritta of Pt. Khushilal Sharma Govt. Ayurveda, Bhopal. **Group A:** *Yogasana* and *AmalakiChurna* Group. **Group B:** *AmalakiChurna* Group

- *Trikonasana, Pawanmuktasana, Janushirshasana, Marichyasana, Setubandhasana, Ushtrasana, Mandukasana*, for 7 times early in the morning daily for 45 days.
- In both the groups, Oral administration of *AmalakiChurna* in 6gm BD dose daily empty stomach with luke warm water for 45 days.
- In both the groups, Pt. advised for restriction of diet according to D.M.

Out of these patients 45 were completed the course of treatment and 15 patients were dropout due to inconvenience for regular yoga practice. Statistical analysis of both the group showed that Yoga therapy and *AmalakiChurna* provided relief in all subjective and objective parameter in Type 2 DM. On inter group comparison of group A and B, group A showed better effect than group B. This shows that specific *YogaTherapy* and *AmalakiChurna* was effective in control of Type 2 DM.

Key Word: Type 2 DM, *Yoga Therapy*, *AmalakiChurna*.

INTRODUCTION:

The prevalence of Diabetes is rapidly rising all over the globe at an alarming rate.^[1] Diabetes Mellitus occurs throughout the world, but it is more common; especially Type-2 Diabetes Mellitus in the developed countries. WHO predicted that 30 million people were diagnosed with Diabetes worldwide in 1985, by 1995 the number had risen to 135 million and at the current rate there will be some 592 million by the year 2035.^[2] In India, it is estimated that by the year 2017 total number of Diabetic subjects to be around 72.9 and by year 2045 it is further set to rise to 134.3 million (IDF).^[3]

Diabetes is a lifestyle disease and it can affect people at any age, leading to many complications like heart disease and kidney disease etc. One way to keep Diabetes and its complications under control is; early detection of the disease

and to adopt the healthy lifestyle. According to the Modern science, main two type of Diabetes are referred as Type-1 DM & Type-2 DM.

The ancient Indian physicians also had a sound knowledge of Diabetes. It is considered as one of the serious disease and included in '*AshthaMahagada*'. In *Ayurveda*, types, clinical features, complications and treatment of Diabetes described vividly. Both *Sushruta* and *Charaka* emphasized the importance of diet and exercise in the management of Diabetes.

Various scientific researches showed *Yogasanas* have great potential in the prevention and the control of lifestyle disorders like metabolic syndrome, asthma, cancer, diabetes and its co-morbid conditions like hypertension and dyslipidemia etc.^[4] Simultaneously, Various Ayurvedic single herbs proved its potential in the control of Diabetes and its complications. *AmalakiChurna* is one of

them *Acharya* have described *Amalaki* as an antidiabetic (*Pramehaghna*) drug on the basis of its pharmacological properties. (*B.P. Hrit.3/39 p-9-12*). Thus for the present study Specific yoga therapy and *AmalakiChurna* were selected for the patients of Type 2 DM.

MATERIALS & METHOD

Plan of Study:

It is a clinical study and the sample was selected from simple random sampling technique. The diagnosed cases of type 2DM and those who are already under the treatment and taking modern oral hypoglycemic drug was considered for intervention. Patients were advised to continue same oral hypoglycemic drug with same dose as was before the initiation of present trial regimen.

Ethical Clearance

The proposed clinical study was presented in the form of a synopsis in front of Institutional Ethics Committee. The clinical trial started after the approval from Chairman of Institutional Ethics Committee.

AIM AND OBJECTIVE:

1. To evaluate the combine efficacy of *Yogasana* and *AmalakiChurna* in the management of Type-2 Diabetes cases.
2. To evaluate the efficacy of *AmalakiChurna* in the management of Type-2 Diabetes cases.

METHOD

Sample Size: Total 60 male patients (30patients in each group).

Grouping

Group A:
Yogasana and *AmalakiChurna* (YAC) Group

Group B: *AmalakiChurna* Group

- *Anulomavilomapranayama* for 10minutes.
- *Trikonasana, Pawanmuktasana, Janushirshasana, Marichyasana, Setubandhasana, Ushtrasana, Mandukasana*, for 7 times early in the morning daily for 45 days.
- In both the groups, Oral administration of *AmalakiChurna* in 6gm BD dose daily empty stomach with luke warm water for 45 days.
- In both the groups, Pt. advised for specific Diabetic diet.

Inclusion criteria

- The Male patients of Age group between 25-60 years.
- The male patients Plasma glucose level :
 - Fasting (8 hour) : > 126-140 mg/dl
 - Post prandial after 2 hour : > 200 mg/dl

Exclusion criteria

- Female Patients
- Patients below the Age 25years and above 60 years.
- Patients with Type 1 Diabetes Mellitus (IDDM).
- Patients having secondary Diabetes Mellitus.
- Patients suffering from any severe systemic illness.

Investigation

- FBS & PPBS

Blood sample was collected up to 2-4ml. as per requirement

CRITERIA FOR ASSESSMENT

Subjective Assessment: To assess the subjective features and the clinical symptoms, which so ever presented by the patients, were graded in to four grades (0-3) scale on the basis of severity, before and after the completion of treatment plan.

Grade Complaint

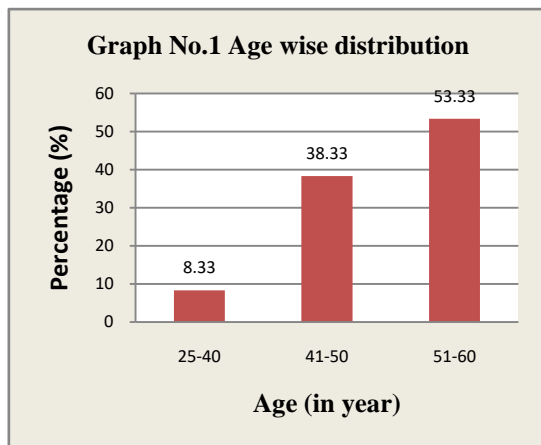
0 No complaint

- 1 Presence of mild complaint
- 2 Presence of moderate complaint
- 3 Presence of severe complaint

Objective Assessment

- Fasting Plasma Glucose
- Post prandial

Graph Pad InStat-3 software was used for statistical analysis

OBSERVATION AND RESULTS:

In this study maximum no. of patients 96.66 % were belonging to urban habitat and least 3.33 % patients were belonging to rural area(Tab.1).55 % patients having family history of *Prameha*, while 45 % patient were found no family History of *Prameha*(Tab.2).In the present study maximum number of patients 43.33% were belonging to *Kapha -Vat Prakriti*, 35 % patients were belonging to *Pitta-KaphajPrakriti* whereas 21.66 % patients were belonging to *Vat-PittaPrakriti*.(Tab.3)Thishshows that incidence of disease is maximum when there is dominance of vata and kapha in the body constitution.Nidanwise

In this study, total 60 patients were registered and Out of 60patients, 45 cases turned up for follow-up and 15 patients were dropped.

In this study the majority of the patients53.33%were reported in the age group of 51-60yrs followed by 38.33% in the age grp of 41-50yrs and 8.33% in the age group of 25-40 yrs.(Graph no.1).

distribution shows that most of the DM. patient were consuming Guru,Snigdha, Sheeta,

Madhura,Amala,Lavanapredominant

Ahara regularly which are consider the main causative factor of this disease.Asyasukham, ayayama, Achinta and Diwaswapana are the major Viharatmakanidas found in this study. This confirms that Lack of exercise,Sedentary lifestyle and physical inactivity are causative factors for Type 2DM.(Tab.4&5)

Effect of therapy on Subjective parameter- On intra group comparison in both the groups, mean difference of all the

symptoms i.e. *PrabhutMutrata*, *AvilMutrata*, *KshudhaAdhikya*, *TrushnaAdhikya*, *Gal-TaluShosha*, *Kar-Pad dhaha*, *Kar-Pad shuptata*, *Pindikouvestana*, *NishaMutrata*, *Daurbalya* was reduced after treatment and found statistically extremely significant, very significant and significant which indicates the efficacy of the treatment. On inter group comparison of group A and group B effect of treatment on subjective parameters showed that mean difference of grp. A is more than grp. B so it can be inferred that group A is better than group B in all subjective parameters. (Tab.6)

Effect on FBS & PPBS- On intra group comparison, both the groups showed reduction in FBS but statistically mean difference of FBS before treatment and after treatment was found not significant. On inter group comparison of group A and group B effect of treatment on FBS, both the groups showed unequal result with statistically extremely significant difference ($p < 0.0001$). Mean difference of FBS in Group A was 80.74 and in group B was 6.100. So we can say that improvement of FBS in Group A is better than Group B. (Tab.7). On intra group comparison of PPBS in both the groups before treatment and after treatment showed statistically significant result. On inter group comparison of group A and group B, effect of treatment on PPBS, both the groups showed unequal result with statistically extremely significant difference ($p < 0.0001$). Mean difference of PPBS in Group A was 117.55 and in group B was 18.384. So we can say that improvement of PPBS, Group A is better than Group B. (Tab.8)

<i>DehaPrakriti</i>	No. of Patients	Percentage (%)
<i>VataPitta</i>	13	21.66
<i>PittaKapha</i>	21	35.00
<i>KaphaVata</i>	26	43.33
Total	60	100

Table No.1 Habitat wise distribution of patients.

Habitat	No. of Patients	Percentage (%)
Rural	2	3.33
Urban	58	96.66
Total	60	100

Table No.2 Family History wise distribution of patients

Family History	No. of Patients	Percentage (%)
Absent	27	45.00
Present	33	55.00
Total	60	100

TableNo.3Prakriti wise distribution of patients.**Table No.4 Aharatmaka Nidana wise distribution of patients.**

AharatmakaNidana	No. of Patients	Percentage (%)
Guru Ahara	42	70.00
SnigdhaAhara	39	65.00
SheetaAhara	35	58.33
MadhuraAhara	41	68.33
AmlaAhara	18	30.00
LavanaAhara	26	43.33
Kshira/Ghrita/Dadhisevan	30	50
Gramya/Anupa/Audaka-MamsaAhara	26	43.33

Table No.5ViharatmakaNidana wise distribution of patients.

Viharatmaka Nidana	No. of Patients	Percentage (%)
Avyayama	37	61.66
Diwaswapa	20	33.33
AsyaSukha	41	68.33
Achinta	26	43.33

Table No.6 Effect of treatment on Sign and Symptoms.

Sign and Symptoms	Group	Mean		MD	% Relief	SD	SE	Wilcoxon matched-pairs signed & p value
		BT	AT					
PrabhutMutarata (Polyuria)	A (n=20)	1.150	0.2000	0.9500	82.60	0.8256	0.1846	W=105, N=14 p<0.0001,ES****
	B (n=25)	0.8400	0.4000	0.4400	52.38	0.5831	0.1166	W=55, N=10 P=0.0020,VS**
Mann- Witney U-statistic = 161.5, p = 0.0451, S*								

<i>AvilMutrata</i> (Turbidity of Urine)	A (n=20)	0.9000	0.1500	0.7500	83.33	0.9665	0.2161	W= 45, N=9 P=0.0039, VS***
	B (n=25)	0.8000	0.5600	0.2400	30.00	0.4359	0.0871	W=21, N=6 P= 0.0313, S *
	Mann- Witney U-statistic = 182.5, p = 0.1164, NS							
<i>KshudhaAdhikya</i> (Polyphagia)	A (n=20)	1.000	0.1500	0.8500	85.00	0.5871	0.1313	W=120, N=15 p<0.0001, ES****
	B (n=25)	1.000	0.4400	0.5600	56.00	0.6506	0.1301	W=78, N=12 p=0.0005, ES***
	Mann- Witney U-statistic = 182.5, p = 0.1382 NS							
<i>TrushnaAdhikya</i> (Polydipsia)	A (n=20)	1.250	0.2000	1.050	84.00	0.8870	0.1983	W=105, N=14 p<0.0001, ES****
	B (n=25)	1.040	0.5600	0.4800	46.15	0.5099	0.1020	W=78, N=12 P=0.0005, ES****
	Mann- Witney U-statistic = 159, p =0.0361 S*							
<i>Gal-TaluShosh</i> (Dryness of mouth)	A (n=20)	0.7500	0.0500	0.7000	93.33	0.4702	0.1051	W=105, N=14 p<0.0001, ES****
	B (n=25)	0.8000	0.3600	0.4400	55.00	0.5831	0.1166	W=55, N=10 P=0.0020, VS**
	Mann- Witney U-statistic = 182, p = 0.1172 NS							
<i>Kar-Pad dhah</i> (Burni ng sensation in palms & sole)	A (n=20)	1.000	0.1500	0.8500	85.00	0.6708	0.1500	W=105, N=14 p<0.0001, ES****
	B (n=25)	1.000	0.3600	0.6400	64.00	0.7000	0.1400	W=91, N=13 P=0.0002, ES***
	Mann- Witney U-statistic = 206.5, p = 0.3197 NS							
<i>Kar-Pad Suptata</i> (Numbness in hands & feet)	A (n=20)	0.7500	0.1000	0.6500	86.66	0.8127	0.1817	W=55, N=10 P=0.0020, VS*
	B (n=25)	0.8800	0.2800	0.6000	68.18	0.6455	0.1291	W=91, N=13 P=0.0002, ES***
	Mann- Witney U-statistic = 249, p = 99.07NS							
<i>Pindikoudvestanah</i> (Cramps in legs)	A (n=20)	1.250	0.3500	0.9000	72.00	0.5525	0.1235	W=136, N=10 p<0.0001, ES****
	B (n=25)	0.9200	0.4000	0.5200	56.52	0.5859	0.1172	W=78, N=12 P=0.0005, ES***
	Mann- Witney U-statistic = 166, p = 0.0528 CNS							
<i>NishaMutrata</i> (Nocturia)	A (n=20)	1.300	0.2500	1.050	80.76	0.8870	0.1983	W=105, N=14 p<0.0001, ES****
	B (n=25)	1.080	0.5200	0.5600	51.85	0.6506	0.1301	W=78, N=12 P=0.0005, ES***
	Mann- Witney U-statistic = 190, p = 0.0732 NS							
<i>Daurbalya</i> (General debility)	A (n=20)	1.200	0.2000	1.000	83.33	0.8584	0.1919	W=105, N=14 P<0.0001, ES****
	B (n=25)	0.8400	0.3200	0.5200	61.90	0.7703	0.1541	W=55, N=10 P=0.0020, VS**
	Mann- Witney U-statistic = 165.5, p = 0.0521 NS							

Table No.7 Effect on FBS

Group	Mean		MD	SD	SE	Paired t test	p value
	BT	AT					
A (n=20)	177.23	96.49	80.74	57.29	12.81	t=6.302	p=0.001, ES***
B (n=25)	140.31	134.21	6.100	22.78	4.55	t=1.338	p=0.1933, NS (p>0.05)
Unpaired t test p<0.0001, t =5.316 ES*****							

NOTE : p <0.0001 ES ****, p = 0.0001 to 0.001 ES ***, p >0.05 NS

Table No.8 Effect on PPBS

Group	Mean		MD	SD	SE	Paired t test	p value
	BT	AT					
A (n=20)	267.01	149.47	117.55	95.09	21.263	t=5.528	p<0.0001, ES*****
B (n=25)	211.55	193.16	18.384	39.10	7.820	t=2.351	p=0.0273, S*
Unpaired t test p<0.0001, t =4.332 ES*****							

NOTE : p <0.0001 ES ****, P= 0.01 to 0.05 S*

DISCUSSION

Possible Justification for effect of therapy:

- Excessive formation of *Kleda* and *Ama* in the body causes increased frequency and quantity of urination. Regular *Yoga* practice improves the *Agni* and tones the internal organs and *Amalaki* due to *Kashaya*, *Tiktta* and *KatuRasa* acts as *Sangrahi* and *Kleda*, *Meda*, *ShlesmaShoshaka* thus reduces the symptom ***PrabhutaMutrata***.
- ***Galatalushosha*** are the result of excessive excretion of *DravyaDhatu* through *PrabhutaMutrata*. As both the therapy showed improvement in *PrabhutaMutrata* simultaneously it reduces ***Galatalushosha***.
- *Amalaki* has *Deepana* and *KashayaRasa* property due to its *VishadaGunait* clears the fluid, increase *Malotpatti* thus decreases the excess of *Kleda* and ***AvilaMutrata***.
- Vitiated *Kapha* and *MedaDhatu* obstruct the channels so the *VataVridhhi* occurs. *Amalaki* and *Yoga* therapy improves the status of *Agni*, Cleans the *Strotus* so improvement in ***Kshudhaadhikya*** was observed.
- *Amalaki* has *Mridurechana* and *SheetaVeerya* thus pacifies the *Pitta* which is responsible for ***Karpaddaha***.
- ***Karpadsuptata*** occurs due to inactivity of nerves due to *Shrotorodha* of *Kapha*. *Yoga* improves the circulation and *Amalaki* had *Strotoshodhana*, *Tridoshashamak*, *Rasayana* property. Therefore it might have produced proper *Dhatu* and improved *Rasaraktsamvahana*. So they helped to diminish ***Karpadshuptata***.
- *Yoga* therapy improves blood supply to muscles and produces muscular relaxations and *Rasayana*, *Balya* and *Tridoshaghna* property of *Amalaki* helps to cure ***Pindikodwestana***.
- ***Daurbalya*** is produced due to inadequate nourishment of the *Dhatu*. As *AmalakiChurna* has *Rasayanapr* operty and regular *Yoga* therapy help to utilize the unspent glucose in the release energy hence cure the ***Daurbalya***.
- **FBS & PPBS** - Though both fasting and post-prandial sugar are present in blood, there mechanism of production is quite different. As fasting blood sugar is increased due to inadequate suppression of gluconeogenesis i.e. insulin deficiency and post-prandial blood glucose is increased due to reduced peripheral utilization of glucose i.e. insulin resistance. ^[5] *Yoga* therapy reduces the glucagons and possibly improving the insulin action responsible for reduction in FBS. Improved blood supply to muscles through *yoga* might enhance insulin receptor causing increased glucose uptake by muscles and reduces the PPBS. ^[6] *Amalaki* primarily contains tannin, alkaloids, phenolic compounds, amino acids and carbohydrates. It is rich in chromium and contains many nutrients like Vit.C, Vit.B, calcium phosphorus, iron and

carotene.. It plays a role in reducing oxidative stress and improving glucose metabolism in type 2 DM.^[7]

Conclusion:

➤ Intake of *Guru, Snigdha, MadhurAhara* and Sedentary Lifestyle are the main etiological factors for Type-2 Diabetes Mellitus.

➤ Study group kept on specific *Yoga Therapy* and *AmalakiChurna* showed better effects with respect to subjective and objective parameters in Type-2 Diabetes Mellitus.

➤ Interventions like *Yoga* therapy and *Rasayana* therapy (*AmalakiChurna*) are useful as an add on therapy for control of Type-2 Diabetes Mellitus.

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