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Clinical evaluation of *Virecana Karma* and *Ayaskriti* in the management of *Prameha* vis-a-vis Type-2 Diabetes

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Abstract

Diabetes mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. Depending on the aetiology of the DM factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization, and increased glucose production. The *Virecana Karma* (cellular biopurificatory measures) of *Ayurveda* is claimed to produce cellular cleansing effect, promoting mobilization of essential nutritional pool and immune enhancing effect. Such a line of management is preferred in *Ayurveda* because of *Srotodusti* and accumulation of metabolic waste products (*Ama*) are the main culprit in the diathesis of disease, which is of great significance in case of type-2 Diabetes mellitus. Considering this fact, the present study had been under taken to conduct clinical assessment of the role of *Virecana Karma* (*shodhana Therapy*) & *Ayaskriti* (*Samana Therapy*) in cases of type 2 diabetes. During this study it was found that only with the help of complete ayurvedic measures i.e *Samsodhan* & *Samana* measure (*Virecana karma* & *Ayaskriti*) there was fall in Blood sugar level in Type-2 DM as well as lipid profile & clinical symptoms were also improved.

Keywords: *Prameha*, Diabetes Mellitus, *Virecana*, *Samana*, *Shodhan*

1. Introduction

DM-2 is one of the major clinically entity, which have been vividly described in *Ayurvedic* classics in the context of *Prameha* striking resemblance with the available latest knowledge in this field. The causes of DM-2 are comparable to the disease entity *Prameha/Madhumeha* in *Ayurveda*. Life style errors are the major etiological categories described for *Prameha*, which is closely resemblance with the etiology of DM-2 [1]. The *Ayurvedic* text also describes the pathogenesis of *Prameha*/DM-2 an extremely evolved manner, involving the 3 *Dosha* and 10 *Dusya* [2]. Although it is a *Tridoshik* disorders but *Kapha Dosha* is the main initiating factors in the genesis and diathesis of DM-2/*Prameha* [3]. The involvement of a wide range of *Dusyas* (ranging from *Rasa* to *Ojas*) indicates that *Prameha* is a systemic disease involving the whole body [4]. Nowadays, Diabetes Mellitus is becoming a great problem for society causing impediment in normal life [5]. In present research work, an attempt is made to prove noble remedy from indigenous system for the management of Diabetes Mellitus. After *Samsodhan* by *Virecana karma*, *Ayaskriti* which has been mentioned by *Astangahridaya* was administered to the patients [6].

Aims and Objectives

- To reflect an over view on the concept of DM-2 vis-à-vis *Prameha*.
- To study the hypoglycemic effect of *Virecana Karma* & *Ayaskriti* on subjective and objectives parameters.
- To develop *Virecana Karma* & *Ayaskriti* as preventive and/or curative measures in DM-2.

2. Material and Method

2.1 Selection of cases

Cases of DM-2 were selected randomly from OPD and IPD of *Kayachikitsa (Panchkarma)*, S.S. Hospital, IMS, B.H.U. Varanasi from august 2013 to September 2014 after thorough history taking, clinical and laboratory examination. Most of the patients were come to this hospital directly, while some of them were referred cases from other medical centers or from local doctors.

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2.2 Diagnostic Criteria

Patients of different age group, sex and socio-economic status were selected from the *Kayachikitsa (Panchkarma)* OPD & IPD, S.S. Hospital, IMS, BHU, on the basis of following criteria.

2.3 Inclusion criteria

- Age 30-60 yrs.
- Family History of Diabetes, HTN, Dyslipidemia
- Plasma glucose level:
Fasting: ≥ 126 mg/dl
Postprandial: ≥ 200 mg/dl
HbA1c: ≥ 6.5%
BMI: 18.5 – 29.9
- Patients having classical symptom of diseases without marked weight loss.

2.4 Exclusion criteria

- Age <30yrs. and >60yrs.
- Type 2 Diabetes Mellitus with complications.
- Type 1 Diabetes Mellitus associated with and without complications.
- Diabetes due to endocrinopathies e.g. Pheochromocytoma, Acromegaly, Cushing’s syndrome, hyperthyroidism etc.
- Drug or chemical induced diabetes mellitus e.g. Glucocorticoids, Thyroid hormone, Thiazides, Phenytoin etc.
- Certain genetic syndromes sometimes associated with diabetes mellitus e.g. Down’s syndrome, Klinefelter’s syndrome, Turner’s syndrome etc.
- Patients suffering from any severe systemic disease.
- Patient having fasting blood glucose level ≥ 250mg/dl and pp blood sugar ≥350.

2.5. Investigation

Blood Examination

Routine blood was examined for total leukocyte count, differential leucocytes count, hemoglobin percentage and erythrocyte sedimentation rate to exclude any infection. Blood urea and serum creatinine were done to assess the renal status. Liver function test.

Urine Examination

Urine for each case was examined for specific gravity, reaction, sugar, albumin and acetone routinely and microscopic examination for crystals, casts and cells.

2.6 Study design and treatment schedule

A total 20 patients with evidence of DM-2 and fulfilling the proposed criteria of selection were enrolled for clinical trial "Clinical evaluation of *Virecana Karma and Ayaskriti* in the management of *Pramehavis-a-vis* Type-2 DM."

All these 20 cases were treated with *Virecana karma* with *Trivritadi Leham* (50gm) & then *Ayaskriti* 20ml bid after meal.

2.7 Assessment criteria

The assessment of the treatment was based on both subjective and objective parameters.

i. Subjective Assessment

This completely depends upon the symptomatology and its grades. Improvement in symptoms is directly proportional to

the improvement in the patient’s condition and his metabolic state. To assess the subjective features of DM-2, the clinical symptomatology was graded into four grades (0-3) scale on the basis of severity and duration. The changes in the gradations of each symptom were noted on a prepared protocol to assess the therapeutic response of trial treatment.

The clinical gradations of symptoms were as follows.

- 0 : No symptom present.
- 1 : Mild symptoms present.
- 2 : Moderate symptoms present
- 3 : Severe symptoms present.

ii. Objective Assessment

Objective assessment was done on the following basis

- Weight
- BMI (body mass index)
- Fasting blood Glucose
- Postprandial blood Glucose
- Serum Cholesterol
- Serum Triglyceride
- Serum LDL
- HbA1c

2.8 Follow up Studies

After the initial registration and basal study, all the patients were recruited in trial groups and given the treatment regularly as per schedule. They were advised to come after 1 month interval for the assessment of therapeutic response. Total duration of study was 90 days. For each follow up of 30 days, the patients were assessed for clinical symptoms, including physical examination; estimation of blood sugar (Fasting and Postprandial) while status of *HbA1c*, BMI, Sr. Cholesterol, Sr. Triglyceride & Sr. LDL were assessed before and after the treatment.

3. Therapeutic Studies and Clinical Trial

Table 1: Polydipsia

No. of Cases (%age) n=20					Within the group comparison (Friedman Chi-square)
Grade	BT	F1	F2	F3	
0	0	3	4	10	$\chi^2=29.38$ P<0.001 HS
1	6	7	12	10	
2	12	8	4	0	
3	2	2	0	0	

Table 2: Burning sensation

No. of Cases (%age) n=20					Within the group comparison (Friedman Chi-square)
Grade	BT	F1	F2	F3	
0	2	6	11	17	$\chi^2=39.39$ P<0.001 HS
1	7	13	8	3	
2	7	1	1	0	
3	4	0	0	0	

Table 3: Weakness

No. of Cases (%age) n=20					Within the group comparison (Friedman Chi-square)
Grade	BT	F1	F2	F3	
0	0	3	7	16	$\chi^2=42.46$ P<.001 HS
1	5	15	10	4	
2	10	2	2	0	
3	5	0	1	0	

Table 4: Polyurea

No. of Cases (%age) n=20					Within the group comparison (Friedman Chi-square)
Grade	BT	F1	F2	F3	
0	0	2	6	12	$\chi^2=33.56$ P<0.001 HS
1	7	8	13	6	
2	8	9	1	2	
3	5	1	0	0	

Table 5: Polyphagia

No. of Cases (%age) n=20					Within the group comparison (Friedman Chi-square)
Grade	BT	F1	F2	F3	
0	2	0	4	9	$\chi^2=14.11$ P<0.001 HS
1	6	12	10	7	
2	9	5	5	4	
3	3	3	1	0	

Table 6: Effect of treatment on FBS

FBS Mean \pm SD				Within the group comparison, Paired 't' test, (BT - FU3)
BT	FU1	FU2	FU3	
199.55 \pm 39.16	122.05 \pm 30.71	104.0 \pm 18.38	92.75 \pm 9.99	106.80 \pm 35.61 t = 13.41 P < 0.001 HS

Table 7: Effect of treatment on PPBS

PPBS Mean \pm SD				Within the group comparison, Paired 't' test, (BT - FU3)
BT	FU1	FU2	FU3	
282.25 \pm 54.32	166.80 \pm 37.77	127.3 \pm 21.69	122.40 \pm 13.72	159.85 \pm 49.49 t = 14.44 p < 0.001 HS

Table 8: Effect of treatment on Sr. Cholesterol

Sr. Cholesterol Mean \pm SD		Within the group comparison, Paired 't' test, (BT - AT)
BT	AT	
272.90 \pm 40.78	147.77 \pm 12.95	125.1 \pm 29.7 t = 18.82 p < 0.001 HS

Table 9: Effect of treatment on Sr. Triglyceride

Sr. Triglyceride Mean \pm SD		Within the group comparison, Paired 't' test, (BT - AT)
BT	AT	
224.75 \pm 39.01	125.9 \pm 24.97	98.8 \pm 36.42 t = 12.13 p < 0.001 HS

Table 10: Effect of Trial Treatment on Sr. LDL

Sr. LDL Mean \pm SD		Within the group comparison, Paired 't' test, (BT - AT)
BT	AT	
191.30 \pm 34.43	89.4 \pm 12.65	101.1 \pm 23.84 t = 19.10 p < 0.001 HS

Table 11: Effect of Trial Treatment on HbA1c

HbA1c Mean \pm SD		Within the group comparison, Paired 't' test, (BT - AT)
BT	AT	
8.35 \pm 1.71	6.97 \pm 1.18	1.37 \pm .824 t = 7.443 p < 0.001 HS

Table 12: Effect of treatment on BMI

BMI Mean \pm SD		Within the group comparison, Paired 't' test, (BT - AT)
BT	AT	
26.72 \pm 1.41	23.57 \pm 2.04	3.15 \pm 1.86 t = 7.55 p < 0.001 HS

6. Results & Discussion

It was observed that, there were statistically highly significant improvement in Polydipsia, Burning sensation, Weakness, Polyurea, Polyphagia (P < 0.001) as well as in BMI (P < 0.001). *Virecana karma* & *Ayaskriti* had shown a good degree of difference in BMI level (3.151 \pm 1.86). In this series the mean reduction in fasting blood sugar was found to be statistically significant. The absolute changes in fasting blood sugar was 106.80 \pm 35.61 (p < 0.001). The absolute fall in PP blood sugar was 159.85 \pm 49.49 (P < 0.001). This indicates that with the help of *Ayurvedic* therapeutic measures we can well control blood sugar level and improves the clinical symptoms along with weight loss. The serum cholesterol, serum triglyceride & serum LDL level of patients showed highly significant changes (P < 0.001). HbA1c shows difference of 1.37 \pm .824 BT to AT.

7. Conclusion

Only with the help of complete ayurvedic measures i.e *Samsodhan* & *Samana* measure (*Virecana karma* & *Ayaskriti*) not only fall in Blood sugar level in Type-2 DM but lipid profile & clinical symptoms also improved. This suggested the selected *Virecana karma* measures cleans the body channels and potentiate the peripheral utilization of glucose and due to peripheral utilization of glucose, lipid contents also get improved. In this study, the selected *Virecana karma* and *Ayaskriti* not only have encouraging results in terms of well control blood sugar level along with weight loss but also seems to be helpful to check the complications in Type-2 DM. Thus, these two approaches of *Ayurvedic* classics have significant preventive & curative role in DM-2. This work open new *Ayurveda*-inspired holistic approach to the management of Type 2 Diabetes Mellitus.

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