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# Comparative study of *Virecana Karma and Oral Hypglycemic Agent with Virecana Karma and Ayaskriti* in the management of *Prameha* w.s.r Type-2 Diabetes.

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**Abstract:** Diabetes Mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. Several distinct types of DM are caused by a complex interaction of genetics and environmental factors. 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 (*Àma*) 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 (shodhan Therapy)* & *Ayaskriti(Samana Therapy)* in cases of type 2 diadetes. 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.

Key words: *Prameha,* Diabetes Mellitus, *Virecana, Samana, Shodhan*

**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. The *Ayurvedic* text also describes the pathogenesis of *Prameha*/DM-2 an extremely evolved manner, involving the 3 *Dosha* and 10 *Dusyas*. Although it is a *Tridoshik* disorders but *Kapha Dosha* is the main initiating factors in the genesis and diathesis of DM-2/*Prameha*. The involvement of a wide range of *Dusyas* (ranging from *Rasa* to *Ojas*) indicates that *Prameha* is a systemic disease involving the whole body. Nowadays, Diabetes Mellitus is becoming a great problem for society causing impediment in normal life. In present research work, an attempt is made to prove noble remedy from indigenous system for the management of Diabetes Mellitus. After *Samshodhan* by *Virecana karma*, *Ayaskriti* which has been mentioned by *Astanga hridaya* was administered to the patients.

In this formulation many *Pramehahara* drugs are present like *Vijayasara, Daruhridara, Karanja, Arjuna, Tinisha, Gudmaar* etc.

**Aims and Objectives**

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

**MATERIAL AND METHOD**

**Selection of cases**

Cases of DM-2 were selected randomly from OPD and IPD of *Kayacikitsa(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.

**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

**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.

**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. Phaeochromocytoma, 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.

**INVESTIGATION**

**1. 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.

**2. 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.

**Study design and treatment schedule**

A total 46 patients with evidence of DM-2 and fulfilling the proposed criteria of selection were enrolled for clinical trial. Out of which 6 cases were dropped out and rest are equally distributed in both the group.

**Group A**: 20 cases were treated with *Virecana karma* with *Trivritadi Leham*(50gm) in classical manner and then OHA was given to 20 patients.

**Group B:** 20 cases were treated with *Virecana karma* with *Trivritadi Leham*(50gm) as per classical text and then *Ayaskriti* was given 20 ml bid after meal.

**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

**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.

**Table 7 Therapeutic Studies and Clinical Trial of Virecana karma and Ayaskriti**

**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 | |

| | | | | | |
|---|---|---|---|---|---|
| 1 | 6 | 7 | 12 | 10 | $\chi^2$ =29.38<br>P<0.001<br>HS |
| 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<br>P<0.001<br>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<br>P<.001<br>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<br>P<0.001<br>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<br>P<0.001<br>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 ±SD | Within the group |
|---|---|

| BT | FU1 | FU2 | FU3 | comparison, Paired 't' test, (BT – FU3) |
|---|---|---|---|---|
| 199.55 ±39.16 | 122.05 ± 30.71 | 104.0 ± 18.38 | 92.75 ± 9.99 | 106.80±35.61 t = 13.41 P < 0.001 HS |

**Table 7 : Effect of treatment on PPBS**

| PPBS Mean ±SD | | | | Within the group comparison, Paired 't' test, (BT – FU3) |
|---|---|---|---|---|
| BT | FU1 | FU2 | FU3 | |
| 282.25 ± 54.32 | 166.80 ± 37.77 | 127.30 ± 21.69 | 122.40 ± 13.72 | 159.85 ± 49.49 t =14.44 p < 0.001 HS |

**Table 8: Effect of treatment on Sr. Cholesterol**

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

**Table 9: Effect of treatment on Sr. Triglyceride**

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

**Table 10 : Effect of Trial Treatment on Sr. LDL**

| Sr. LDL Mean ±SD | | Within the group comparison, Paired 't' test, (BT - AT) |
|---|---|---|
| BT | AT | |

| | | |
|---|---|---|
| 191.30 ± 34.43 | 89.4 ± 12.65 | 101.1 ± 23.84<br>t = 19.10<br>p < 0.001 HS |

**Table 11: Effect of Trial Treatment on HbA1c**

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

**Table 12 : Effect of treatment on BMI**

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

**Observation & Discussion**

The majority of the patients were registered with negative family history (68.33%). 31.67% of total cases had the positive family history of diabetes in their first degree relatives, Besides, it was also observed that maximum no. of DM-2 fall in *Rasa* dominant *Dusya* (58.33%) followed by *Meda* (41.67%).

This indicates that not only familial impact but other factors also kept in mind at the time of describing etiopathogenesis of diabetes. This view is very relevant to concepts of *Prameha* / *Madhumeha* of *Ayurveda*.

The present study shows that the duration of illness in patients of DM-2, 41.67% were newly diagnosed, 31.67% had duration of illness > 3 years, 26.67% patients had duration of illness <3 years. In this, Incidence of clinical symptomatology in patients of DM-2 revealed that the maximum number of patients (93.33%) had Polydipsia followed by Polyurea, Burning sensation, Weakness (95.0%) and Polyphagia (96.67%). This refuse that the clinical features of DM-2 described in *Ayurveda* are very scientific & comparable to the latest knowledge in this field.

In group A, Polyphagia, Polyurea, Polydipsia, Burning sensation and Weakness shows highly significant changes after the completion of treatment The changes of BMI were statistically highly significant (P<0.001). *Virecana karma* and OHA had showed a good degree of difference in BMI level (2.58 ± .888), this indicates that not only familial impact but other factors also kept in mind at the time of describing etiopathogenesis of diabetes. This view is very relevant to concepts of *Prameha* / *Madhumeha* of *Ayurveda*.

**Fasting Blood Sugar:** In this series the mean reduction in fasting blood sugar was found to be statistically significant. The absolute changes in fasting blood sugar was (106.60 ±35.61) ($p<0.001$).

**Postprandial Blood Sugar:** The mean reduction in PP blood sugar was found statistically highly significant. The absolute fall in PP blood sugar was 154.10 ± 53.76 ($P < 0.001$) This indicates that *Virecana karma* along with OHA measures we can well control blood sugar level and improves the clinical symptoms along with weight loss.

Besides this it is also interesting to note that probably *Virecana karma* cleans the body channel and enhances mobilization of blood sugar from central to peripheral compartment either by decreasing insulin resistance or by increasing insulin secretion due to which there is decrement in the dose of OHA.

**Lipid Profile:** In the present study the serum cholesterol, serum triglyceride & serum LDL level of patients showed highly significant changes ($P < 0.001$) due to *Virecana karma* & OHA. This study reveals that the trial treatment have tendency to reduce Serum Cholesterol & Serum TG level in patients Type-2 DM, which is not possible only with the help of only OHA.

**HbA1c:** In the present study, HbA1c shows difference of (1.75 ± 1.08) BT to AT. So it shows that *Virecana karma* with OHA measure can maintain blood sugar level for long term. It shows that Virecana has long term effect because OHA does not have significant effect on HbA1c as described in OHA pharmacology.

In group B, Polyphagia, Polyurea, Polydipsia, Burning sensation and Weakness shows highly significant changes after the completion of treatment. The changes of BMI were statistically highly significant ($P<0.001$). Group B had showed a good degree of difference in BMI level (3.151 ± 1.86), this indicates that not only familial impact but other factors also kept in mind at the time of describing etiopathogenesis of diabetes. This view is very relevant to concepts of *Prameha* / *Madhumeha* of *Ayurveda*.

While studying body weight of the patients it was found that most of them were having weight 71-80 kg (35%) followed by 61-70 kg (31.67%).This is the strong evidence for the obesity as a factor for DM-2. Body mass index was also calculated to identify the exact level of obesity and it was found that maximum patients (44%) were registered as normal (18.5-24.9 $kg/m^2$) followed by 37.33% in over weight category (25.0-29.9 $kg/m^{2)}$ and 18.67% patient were registered under obese category (30.0 – 39.9 $kg/m^2$)

**Fasting Blood Sugar:** 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 ± 35.61($p<0.001$).

**Postprandial Blood Sugar:** The mean reduction in PP blood sugar was found statistically highly significant. The absolute fall in PP blood sugar was 159.85 ± 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.

**Lipid Profile:** In the present study the serum cholesterol, serum triglyceride & serum LDL level of patients showed highly significant changes ($P < 0.001$) due to *Virecana karma* & *Ayaskriti* .This study reveals that the trial treatment have tendency to reduce Serum Cholesterol & Serum TG level in patients Type-2 DM.

**HbA1c:** In the present study, HbA1c shows difference of 1.37 ± .824 BT to AT. So it shows only with *Ayurvedic* measure, we can maintain blood sugar level for long term.

**Safety Profile**

For the safety profile of the patients, we have done Serum Creatinine & Blood Urea, LFT, CBC, ECG and CXR before & after treatment & we did not get any unwanted effect on the major metabolic organs of the body. Therefore this is suggesting that selected *Ayurvedic* measures were safe in regards to renal function, liver function & cardiac function.

**Probable Mode of action of *Virecana karma***

Action of *Virecana* Karma can be divided in the following two ways.

**(1)** **Systemic -** by which it brings down the morbid *Dosha*, particularly *Pitta* from the body to *Amashaya* or *Pakvashaya* i.e. GIT.

**(2)** **Local Evacuant :** Which is concerned with the evacuation of these *Dosha* in form of *Mala* from the gut by Purgation.

As said by *Acharya Sushruta* in the patients of *madhumeha, kapha* and *pitta* are vitiated excessively and they remain in the lower part of the body. *Virecana* karma is the best therapy to eliminate *doshas* from the lower part of the body and it also eliminate both *kapha* and *pitta.*

**Hypothesis regarding *Virecana karma:***

The incretin effect is the process by which oral glucose has a greater stimulatory effect on insulin secretion than intravenous glucose does in humans, this effects seems to be primarily mediated by GLP-1 & GIP. GLP-1 is produced from the proglucagon gene in intestinal L cells & is secreted in response to nutrients.GLP-1 stimulates insulin secretion in a glucose-dependent fashion, inhibits inappropriate hyperglucagonemia, slows gastric emptying, reduces appetite & improves satiety & has beta cell-proliferative, antiapoptotic, and differentiation effect.

The precise mechanism of *Virecana karma's* action is unknown, but it seems that *Virecana karma* also has Incretin effect in terms of Diabetes Mellitus.

1. By increasing the secretion of GLP-1 & GLP.

2. By increasing the t-half life of GLP-1 & GLP by inhibiting its degradation.

3. Virecana karma also has beta cell- proliferative, antiapoptotic and differentiation effects thus; *Virecana karma* shows dramatic results in Diabetes.

**Probable mode of action of Ayaskriti**

**Special Method of Preparation -**Decoction of *Asanadi Gana* (drugs 1 to 23) is first prepared. Jaggery and honey (drugs 25 and 26) are added to the decoction. *Kalka* of *Vatsakadi Gana Dravyas* (drugs 27 to 49) is made separately and added to the decoction. After making iron sheet red hot, it has been dipped into this decoction repeatedly up to the dissolution into decoction, then decoction is used in Dose of 20 ml bid after meal.

*Asanadi gana* is group of 23 drugs which are well described in ancient *Àyurvedic* classics. The ingredients of the *Asanadi gana* are *Asana, Tinisha, Bhojapatra, Svetawaha, Prakirya, Khadira* etc. Many of these drugs have antidiabetic, hypolipedemic property.

**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 contrast to this study, previous studies also reveal the same & one may also suggest that *Ayaskriti* potentiate the Insulin action centrally as well as peripherally.

The Present study reveals that *Type-2 DM* was well conceived in *Ayurvedic* lexicons in the context of *Prameha*. In *Ayurveda*, *Vyadhi Kriyakala* described by *Sushruta* gives an idea about the consecutive stages of the disease and accordingly management measures can be contemplated to control DM-2 & also to overcome complications. Early diagnosis of disease helps to cure the disease successfully without its progression. *Vyaktavastha* stage of *Kriyakala* represents *symptomatic stage* which indicates the presence of disease. So prescription of medication in the form of *Shodhan chikitsa*(*Virechan karma)* is more important for controlling the disease process and stop its progress further to complication stages.

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. Besides, this studies also overview that if *Virecana karma* and *Ayaskriti* applying in DM-2, it normalise the blood sugar and also cut off its progression to insulin dependence. Thus, these two approaches of *Ayurvedic* classics have significant preventive & curative role in DM-2.

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