Clinical Research

A clinical study on the effect of *Rishyagandha (Withania coagulans)* in the management of *Prameha* (Type II Diabetes Mellitus)

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Abstract

The study was conducted with an objective of evaluating the role of *Rishyagandha (Withania coagulans)* powder in clinically diagnosed cases of *Prameha*. 53 Registered cases were divided into 3 groups; Group A (*Rishyagandha* fruits powder), Group B (Oral Hypoglycaemic Agent i.e. OHA), and Group C (*Rishyagandha* fruits powder and OHA both). Statistically significant improvement was observed in objective and subjective parameters in all 3 groups after completion of the course of treatment. Based on the results, it has been concluded that, *Rishyagandha* fruits powder is an effective therapeutic regimen in the management of uncomplicated cases of *Prameha*.

**Key words:** Diabetes mellitus, oral hypoglycaemic agents, *Prameha*, *Rishyagandha*

Introduction

Ayurveda recognized, *Prameha* as a disease entity in distant past. Among several health problems *Prameha*, is considered as one of the arch enemy of the mankind. *Prameha* comprises a number of diseases with various physical and chemical changes in urine. The manifestation of the disease is described as “*Prabhutavilmutrata,*” which means frequent and copious urine with turbidity.¹² It is also believed that, if not cured or treated properly in due course of time, *Prameha* changes in *Madhumeha*, which is very similar to diabetes mellitus, the most debilitating disease.⁴

Diabetes mellitus is a metabolic disorder characterized by polyuria, polydipsia, hyperglycemia, glycosuria, and generalized weakness may be associated with weight loss. This is the disease that affects every tissue and every organ of the body and is responsible for significant morbidity, reduced life expectancy, and diminished quality of life. It has been seen that there is no any organ or system spared from the diabetic complications, such as nephropathy, neuropathy, retinopathy, and so on. So there is a need for effective drugs for controlling Diabetes and preventing undesirable complications.

Although the introduction of many oral hypoglycemic agents and insulin in modern medical science have great importance in the management of Diabetes, the hazardous effects of these drugs after long term use are incurable or proves many times fatal, hence an ideal therapy is still obscure. Ayurvedic management of Diabetes aims not only to achieve a euglycemic state but also to treat the root cause of disease. There are many medicinal plants mentioned in Ayurvedic texts, particularly in Nighantus having *Pramehahara* property. In the present work, the drug “*Rishyagandha*” (*Withania coagulans*) has been used for the management of *Prameha*. The selected trial drug *Rishyagandha* is mentioned in Charaka Samhita in *Brihaniya Mahakashaya*⁴ and *Madhur a skandha dravya*.⁵

Aims and objectives

Clinical evaluation of *Rishyagandha* fruit powder in the management of *Prameha*.

Drug review

The drug *Rishyagandha* (*W. coagulans* Dunal, family Solanaceae) is mentioned in Charaka samhita in *Brihaniya Mahakashaya* and *Madhur a skandha dravya*. In northern India, its fruits are used in the treatment of *Prameha*.⁶ This plant has the property of coagulating milk, and has been used for preparing a vegetable rennet ferment for making cheese.

Preparation of drug and dosage

Trial drug preparation consists of *Rishyagandha* fruit powder in dose of 10 g daily in 2 divided doses.

Materials and Methods

A series of 53 patients with Diabetes Mellitus were selected from the Outpatient Department (OPD) and Inpatient Department (IPD) of the Department of Kaya Chikitsa, S.S. Hospital,
B.H.U. Most of these cases were known diabetics while some were diagnosed for the first time when they came with other complaints.

**Inclusion criteria**
- Symptoms of diabetes along with random blood glucose concentration ≥11.1 mmol/L (200 mg/dL).
- Fasting plasma glucose ≥7.0 mmol/L (126 mg/dL).
- Two-hour plasma glucose ≥11.1 mmol/L (200 mg/dL) during an oral glucose tolerance test.

**Exclusion criteria**
- All type 1 Diabetes Mellitus cases.
- Cases with complications of the disease or having other associated diseases.
- Cases were excluded from the study which developed complications during the study.

**Grouping of the patients**
Registered patients were into 3
- Group A: Patients who were taking no drug before initiation of therapy, were kept on trial drug.
- Group B: Patients were permitted the OHA with unmodified dose which they were taking before initiation of therapy were treated as the control group.
- Group C: Patients were given a trial drug with the ongoing OHA in the same dose whatever they were taking before the initiation of the treatment.

**Criteria to assess the effect of trial drugs**
All the selected patients have been advised to come for the follow-up for 3 months at regular intervals of 1 month. The clinical grades were decided as follows:

**Polyurea (Frequency of urination)**
- 3–6 times/day, rarely at night
- 6–9 times/day, 0–2 times/night
- 9–12 times/day, 2–4 times/night
- >12 times/day, >4 times/night

**Quantity of urine in liters**
- 1.50–2.00
- 2.00–2.50
- 2.50–3.00
- >3.00

**Polyphagia**
- Normal meal
- Main meal 2, lightbreakfast 2–3/day
- Main meal 2, lightbreakfast 3–5/day
- Main meal 2, lightbreakfast >5/day

**Polydipsia**
- Normal, water intake 2–3 L/day
- Increased, but can be controlled, water intake 3–4 L/day
- Increased frequency without control, water intake 4–5 L/day
- Very much increased, water intake >5 L/day

**Generalized weakness**
- No feeling of weakness

**Burning and tingling sensation**
- No feeling of burning/tingling sensation
- Occasional burning/tingling sensation but not continuous
- Mild, continuous feeling of burning/tingling sensation
- Severe, continuous feeling of burning/tingling sensation

**Joint pain**
- No pain
- Slight pain
- Moderate pain
- Severe pain

**Weight loss (within 1 year)**
- No weight loss
- Weight loss <3 kg
- Weight loss between 3 to 6 kg
- Weight loss >6 kg

**Objective assessment**
- Fasting and postprandial blood sugar have been done in each followup to the completion of study (3 months).
- Routine urine examination in each follow-up.
- Lipid profile in selected cases before and after completion of treatment.
- Regular checkup of body weight in each follow-up.

**Observation and Results**
The observations and results in the study are made on the basis of demographic, constitutional, and clinical profiles of 53 patients having type II diabetes mellitus. Out of 53 patients, 13 patients dropped out the treatment [Table 1].

Maximum cases reported in the study were male (72%). Maximum cases (36%) were of the age group 40–50 years. Most cases (about 77%) were from middle socioeconomic group and maximum cases (about 34%) were businessmen. 32% cases registered were from above graduation group. The study revealed that higher incidence was found in urban dwellers (58%), and incidence in dietary habits was found more in persons with mixed diet (51%). Regarding incidence in physical activities, more patients are mild active (49%).

Maximum cases found (53%) in the study were obese (body mass index >30 kg/m²). About 53% cases belonged to Tamasa Prakriti, and about 45% cases were belonging to kapha Pittaja prakriti.

**Table 1: Therapy wise details of the groups**

| Group | Total no. of registered patients | No. of patients completed the follow-up | Drug |
|-------|---------------------------------|----------------------------------------|------|
| A     | 18                              | 15                                     | Rishyagandha powder |
| B     | 17                              | 12                                     | OraLypoglycaemicgent |
| C     | 18                              | 13                                     | Rishyagandha powder+OHA |
| Total | 53                              | 40                                     |      |
Maximum cases were reported with a positive family history (64%), and the duration of illness was more than 5 years in maximum cases (about 40%).

About 82% cases were presented with weakness followed by about 70% with tingling or burning sensation followed by 62% with polyurea. About 43% cases registered with complaints of joint pain and 32% cases with weight loss. Polyphagia was found in 28% cases and polydipsia in 21% cases, least number of cases (9%) were registered with the complaints of loss of libido.

**Effect of treatment**

As per paired *t* test all the 3 groups (group A, B, and C) showed statistically significant results in the above-mentioned subjective and objective parameters.

**Table 2: Mean change in polyurea**

| Group     | BT  | F1   | F2   | F3   | BT–AT | t test and *P* value |
|-----------|-----|------|------|------|-------|----------------------|
| Group A (n=15) | 1.07 ± 0.96 | 0.80 ± 0.77 | 0.80 ± 0.68 | 0.47 ± 0.64 | 0.60 ± 1.12 | *t=2.07, *P<0.05* |
| Group B (n=12)  | 0.75 ± 0.75 | 0.58 ± 0.67 | 0.67 ± 0.78 | 0.50 ± 0.80 | 0.25 ± 0.45 | *t=1.91, *P<0.05* |
| Group C (n=13)  | 1.08 ± 1.04 | 0.69 ± 0.63 | 0.69 ± 0.63 | 0.38 ± 0.51 | 0.69 ± 0.94 | *t=2.63, *P<0.05* |

AT - After treatment, BT - Before treatment

**Table 3: Mean change in polyphagia**

| Group     | BT  | F1   | F2   | F3   | BT–AT | t test and *P* value |
|-----------|-----|------|------|------|-------|----------------------|
| Group A (n=15) | 0.40 ± 0.63 | 0.27 ± 0.46 | 0.20 ± 0.41 | 0.07 ± 0.26 | 0.33 ± 0.48 | *t=2.65, *P<0.05* |
| Group B (n=12)  | 0.42 ± 0.51 | 0.33 ± 0.49 | 0.33 ± 0.49 | 0.08 ± 0.29 | 0.33 ± 0.49 | *t=2.35, *P<0.05* |
| Group C (n=13)  | 0.46 ± 0.66 | 0.31 ± 0.48 | 0.31 ± 0.48 | 0.15 ± 0.38 | 0.30 ± 0.63 | *t=1.76, *P>0.05* |

AT - After treatment, BT - Before treatment

**Table 4: Mean change in weakness**

| Group     | BT  | F1   | F2   | F3   | BT–AT | t test and *P* value |
|-----------|-----|------|------|------|-------|----------------------|
| Group A (n=15) | 1.20 ± 0.86 | 1.07 ± 0.59 | 0.87 ± 0.52 | 0.40 ± 0.63 | 0.80 ± 1.20 | *t=2.57, *P<0.05* |
| Group B (n=12)  | 1.42 ± 0.79 | 1.33 ± 0.78 | 0.92 ± 0.51 | 0.5 ± 0.67 | 0.83 ± 1.03 | *t=2.80, *P<0.05* |
| Group C (n=13)  | 1.46 ± 0.66 | 1.23 ± 0.60 | 1.15 ± 0.69 | 0.69 ± 0.63 | 0.76 ± 0.92 | *t=2.99, *P<0.05* |

AT - After treatment, BT - Before treatment

**Table 5: Mean change in burning and tingling sensation**

| Group     | BT  | F1   | F2   | F3   | BT–AT | t test and *P* value |
|-----------|-----|------|------|------|-------|----------------------|
| Group A (n=15) | 1.27 ± 0.96 | 0.73 ± 0.70 | 0.67 ± 0.72 | 0.47 ± 0.65 | 0.80 ± 1.26 | *t=2.45, *P<0.05* |
| Group B (n=12)  | 1.17 ± 0.72 | 1.08 ± 0.67 | 1.17 ± 0.58 | 0.92 ± 0.67 | 0.25 ± 1.05 | *t=0.82, *P>0.05* |
| Group C (n=13)  | 0.92 ± 0.86 | 0.85 ± 0.90 | 0.92 ± 0.86 | 0.45 ± 0.78 | 0.38 ± 0.65 | *t=2.13, *P<0.05* |

AT - After treatment, BT - Before treatment

**Table 6: Mean change in joint pain**

| Group     | BT  | F1   | F2   | F3   | BT–AT | t test and *P* value |
|-----------|-----|------|------|------|-------|----------------------|
| Group A (n=15) | 0.40 ± 0.63 | 0.20 ± 0.41 | 0.13 ± 0.35 | 0.07 ± 0.26 | 0.33 ± 0.48 | *t=2.65, *P<0.05* |
| Group B (n=12)  | 0.83 ± 0.94 | 0.42 ± 0.51 | 0.67 ± 0.78 | 0.58 ± 0.79 | 0.25 ± 0.45 | *t=1.91, *P>0.05* |
| Group C (n=13)  | 0.46 ± 0.88 | 0.31 ± 0.63 | 0.38 ± 0.77 | 0.23 ± 0.44 | 0.23 ± 0.43 | *t=1.90, *P>0.05* |

AT - After treatment, BT - Before treatment

**Table 7: Effect of treatment on fasting blood sugar**

| Group     | BT  | F1   | F2   | F3   | BT–AT | t test and *P* value |
|-----------|-----|------|------|------|-------|----------------------|
| Group A (n=15) | 131.50 ± 20.48 | 122.67 ± 19.68 | 122.49 ± 18.16 | 122.35 ± 13.82 | 9.15 ± 13.42 | *t=2.64, *P<0.05* |
| Group B (n=12)  | 148.79 ± 23.17 | 142.41 ± 26.49 | 141.46 ± 18.90 | 141.27 ± 18.58 | 7.52 ± 17.98 | *t=1.45, *P<0.05* |
| Group C (n=13)  | 158.48 ± 54.4 | 146.87 ± 44.46 | 133.39 ± 29.20 | 139.41 ± 39.67 | 19.06 ± 26.64 | *t=2.68, *P<0.05* |

AT - After treatment, BT - Before treatment

Group A showed highly significant relief on polyurea (56.07%), polyphagia (82.50%), weakness (66.67%), burning and tingling sensation (62.99%) and joints pain (82.50%). Group B showed significant result on polyurea (33.33%), polyphagia (78.57%), weakness (58.45%), burning and tingling sensation (21.36%), and joints pain (50.12%). Group C also showed highly significant relief on polyurea (63.88%), polyphagia (65.21%), weakness (52.05%), burning and tingling sensation (41.30%), and joints pain (50.00%) [Tables 2-6]. Effect on blood biochemical parameters of the treatments in all the groups were placed in Tables 6-13.

**Probable mode of action of drugs**

The plant *Rishyagandha* (*W. coagulans* Dunal) is described in *Charaka Samhita* in “Brihaniya Mahakashaya” (a collection...
Table 8: Effect of treatment on postprandial blood sugar

| Group | BT (Mean±SD) | F1 (Mean±SD) | F2 (Mean±SD) | F3 (Mean±SD) | BT-AT (Mean±SD) | t test and P value |
|-------|--------------|--------------|--------------|--------------|-----------------|-------------------|
| Group A (n=15) | 207.53 ± 28.38 | 191.10 ± 20.18 | 186.83 ± 28.68 | 180.29 ± 20.11 | 27.24 ± 24.88 | t=4.24, P<0.001 |
| Group B (n=12) | 233.74 ± 44.33 | 229.08 ± 46.33 | 217.41 ± 40.37 | 215.89 ± 44.53 | 17.85 ± 13.83 | t=4.47, P<0.001 |
| Group C (n=13) | 262.45 ± 72.49 | 233.96 ± 55.58 | 206.72 ± 42.11 | 225.27 ± 43.23 | 37.18 ± 40.39 | t=3.32, P<0.01 |

AT - After treatment, BT - Before treatment

Table 9: Effect of treatment on serum cholesterol

| Group | BT (Mean±SD) | AT (Mean±SD) | BT-AT (Mean±SD) | Paired t test | Paired t test and P value |
|-------|--------------|--------------|-----------------|---------------|---------------------------|
| Group A (n=15) | 176.58 ± 31.72 | 163.44 ± 39.76 | 13.14 ± 27.38 | 1.52 | >0.05 |
| Group B (n=12) | 181.04 ± 42.30 | 174.89 ± 39.36 | −3.47 ± 42.95 | 0.23 | >0.05 |
| Group C (n=13) | 187.38 ± 64.79 | 168.21 ± 46.76 | 19.16 ± 38.43 | 1.41 | >0.05 |

AT - After treatment, BT - Before treatment

Table 10: Effect of treatment on serum triglyceride

| Group | BT (Mean±SD) | AT (Mean±SD) | BT-AT (Mean±SD) | Paired t test | Paired t test and P value |
|-------|--------------|--------------|-----------------|---------------|---------------------------|
| Group A (n=15) | 185.72 ± 96.32 | 139.01 ± 65.11 | 46.91 ± 119.94 | t=1.23 | P>0.05 |
| Group B (n=12) | 173.56 ± 67.21 | 174.89 ± 39.36 | 1.32 ± 35.56 | t=0.11 | P>0.05 |
| Group C (n=13) | 145.11 ± 69.64 | 116.74 ± 39.61 | 28.37 ± 49.01 | t=1.64 | P>0.05 |

AT - After treatment, BT - Before treatment

Table 11: Effect of treatment on serum HDL

| Group | BT (Mean±SD) | AT (Mean±SD) | BT-AT (Mean±SD) | Paired t test | Paired t test and P value |
|-------|--------------|--------------|-----------------|---------------|---------------------------|
| Group A (n=15) | 44.64 ± 5.96 | 51.21 ± 5.20 | 6.57 ± 3.22 | 6.45 | <0.001 |
| Group B (n=12) | 50.21 ± 5.75 | 49.19 ± 5.77 | 1.02 ± 2.56 | 1.13 | >0.05 |
| Group C (n=13) | 40.61 ± 11.04 | 48.38 ± 12.97 | 7.76 ± 10.17 | 2.16 | <0.05 |

AT - After treatment, BT - Before treatment

Table 12: Effect of treatment on blood urea

| Group | BT (Mean±SD) | AT (Mean±SD) | BT-AT (Mean±SD) | Paired t test | Paired t test and P value |
|-------|--------------|--------------|-----------------|---------------|---------------------------|
| Group A (n=15) | 32.21 ± 8.52 | 28.83 ± 9.05 | 3.38 ± 7.11 | 1.84 | >0.05 NS |
| Group B (n=12) | 28.84 ± 8.37 | 27.33 ± 7.71 | 1.50 ± 3.86 | 1.35 | >0.05 NS |
| Group C (n=13) | 30.01 ± 8.62 | 29.72 ± 8.79 | 0.30 ± 5.46 | 0.20 | >0.05 NS |

AT - After treatment, BT - Before treatment

Table 13: Effect of treatment on serum creatinine

| Group | BT (Mean±SD) | AT (Mean±SD) | BT-AT (Mean±SD) | Paired t test | Paired t test and P value |
|-------|--------------|--------------|-----------------|---------------|---------------------------|
| Group A (n=15) | 1.00 ± 0.30 | 0.88 ± 0.24 | 0.12 ± 0.21 | 2.19 | <0.05 |
| Group B (n=12) | 0.83 ± 0.25 | 0.83 ± 0.21 | 0.01 ± 0.14 | 0.12 | >0.05 |
| Group C (n=13) | 0.99 ± 0.52 | 0.80 ± 0.30 | 0.19 ± 0.29 | 2.39 | <0.05 |

AT - After treatment, BT - Before treatment

of drugs, which increases body mass) and “Madhur Skandha Dravya”.

Charaka has described two types of therapies for Prameha, that is, Sambrihana (process which increases body mass), for krisha and dourbala pramehi and Samshodhana (a type of therapy which eliminates impurities from body) for sthula and balvan pramehi.[8] So in krisha and dourbala patient, Rishyagandha improves the quality of dhatu production, promotes the Oja formation, and cures the prameha by its brimhana property.

In sthula pramehi, trial drug acts by the virtue of Dravya prabhava (effect of drug). By dravya prabhava, it acts on the pathogenesis of Madhumeha and breaks down the continuity of Prameha.

Conclusion

It can be concluded from the present study that Rishyagandha fruit powder can be used effectively for a long-term in the treatment of Prameha (Type II Diabetes Mellitus) without any side effects.

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Hindi Saranash

Prameh Chikitsa Mein Oorjagandha Ke Prabhav Ka Chikitsakjy Abhyayan

B. E. UP. UPADHYAY, VANDANA GUSA

Prastut Adhyayan Sar Sundar Lala Chikitsaalya Banaras Hindu Vishwavidyalaya Mein, Oorjagandha Fal Churun Ka Prameh Vyaachi Mein Prabhav Janaane Heto Kiyा Gaya. Iss Adhyayan Ka Pradesh Prameh Rogiyo Ko Sartrti, Prabhavini Va Upadratdheti Chikitsa Uparthod Karyaa Tha. Issme Kular 15 Prameh Rogiyo Ko Adhyayan Heto Jain Kirti Mein Varg Mein Vikshipt Kiyaa Gaya. Varg A Mein Oorjagandha Churun, Varg B Mein Adhunik Aushadh Va Varg C Mein Adhunik Vrddhi Va Oorjagandha Churun Ka Sambhit Prayan Kiyaa Gaya. Iss Adhyayan Mein Oorjagandha Fal Churun Ka Prameh Upchar Mein Kafki Sanktoshjanak Prabhav Deekh Gaya.

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